**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF OHIO**
**EASTERN DIVISION**

**IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION**

**Case No.: 2:18-md-2846**

**JUDGE EDMUND A. SARGUS, JR.**
**Magistrate Judge Kimberly A. Jolson**

**This document relates to:**
**ALL CASES**

# DEFENDANTS C. R. BARD, INC. AND DAVOL INC.'S BRIEF REGARDING THE LACK OF REPRESENTATIVENESS OF *STINSON* AND *BRYAN*

Pursuant to Case Management Order No. 44, Defendants C. R. Bard, Inc. and Davol Inc. (collectively, "Bard") hereby submit their brief on the representativeness of *Stinson* and *Bryan* as bellwether trial cases.

## I. INTRODUCTION

In January 2020, the Court selected four cases to be tried as bellwether cases in this MDL. CMO No. 25, MDL ECF No. 318, at 4. The purpose of selecting bellwether cases is to "provide significant information regarding the entire pool of cases that are part of the MDL." *In re Testosterone Replacement Therapy Prods. Liab. Lit.*, MDL No. 2545, 2017 U.S. Dist. LEXIS 95836, *967 (N.D. Ill. May 22, 2017); *see also* 2/4/2021 CMC Tr., ECF No. 477, at 26:6-11 (noting that the bellwether selection process is intended to identify cases that would allow the parties to evaluate their positions and assess "where the rest of the cases are going to go"). More than three years later, *Stinson* and *Bryan* no longer serve this purpose.

When *Stinson* was selected as a bellwether trial case, it involved the second most commonly alleged device at issue (the PerFix Plug) and his alleged injury (pain) was the most

commonly alleged injury in the MDL. As such, a verdict in *Stinson* would have been instructive as to the strength of claims in and any potential values that should be assigned to a large number of similar cases. Over the course of the last several months, however, Mr. Stinson's medical course has become increasingly complex. Mr. Stinson underwent an additional surgery on May 10, 2023, in which a second Bard hernia device was removed, also resulting in the surgical removal of Mr. Stinson's right testicle and his spermatic cord. As the case now stands, Mr. Stinson has had three surgeries involving two different Bard hernia mesh products and is claiming injuries of not only chronic pain, but also the loss of his testicle and spermatic cord. Further, there is no indication at this early post-operative stage that Mr. Stinson's most recent surgery will alleviate his chronic pain, since one of the procedures he did *not* have was a neurectomy. Mr. Stinson is also at high risk of a recurrent hernia.

In short, *Stinson* no longer remotely resembles a bellwether case that is "representative" of the MDL inventory of cases. According to data from Plaintiff Profile Forms, only 1% of cases in the MDL involve allegations of a loss of testicle[1] and only 10% involve a second device. Regardless of whether Mr. Stinson amends his complaint to assert causes of action based on the Bard Mesh, Plaintiffs indicated at the most recent CMC that they expect the jury to hear evidence and argument about how a second Bard device was explanted and necessitated the removal of Mr. Stinson's testicle and spermatic cord. Not only are these new facts not representative of the other cases in this MDL, they will make any verdict in *Stinson* unhelpful to the larger goals of the bellwether process. *See In re E.I. du Pont de Nemours & Co. C-8*

[1] Based on discrepancies (e.g., ventral rather than inguinal devices), it is likely that this is an over-estimate of the true prevalence of a cases where a testicle was removed in connection with further medical care for injuries for which the plaintiff is suing. However, when looking only at cases in the MDL involving inguinal devices, it is possible that the prevalence of alleged loss of a testicle might fall in the 1-3% range.

*Personal Injury Litig*., 529 F. Supp. 3d 720, 740 (S.D. Ohio 2021). ("Bellwether plaintiffs are purposefully selected to exclude the most severely injured plaintiffs because it would frustrate the bellwether procedure's purpose. That is, the need to try multiple bellwether cases to facilitate settlement of all cases in an important component of the handling an MDL.").

With respect to *Bryan*, it is unclear what Mr. Bryan's current medical status is or what additional treatment he might require (other than that he is seeking a surgery date). In other words, his case is now a moving target. At the time *Bryan* was chosen as a bellwether trial case, Mr. Bryan's primary complaint was pain, although he had not seen a physician for his pain since 2017. Now, Bard understands that, like Mr. Stinson, Mr. Bryan may require additional treatment, including another surgery and the possible removal of Mr. Bryan's testicle. Further, Mr. Bryan has only recently begun to seek additional treatment for his pain and it is likely that it will take several months to determine Mr. Bryan's actual alleged injuries and another several months to conduct the necessary discovery regarding his subsequent medical treatment.[2] And, even if *Bryan* is ready for trial by January 2024, it is not a case Bard would have selected for trial because it is no longer representative.

To further the goals of the bellwether selection process, Bard proposes that the Court replace *Stinson* and *Bryan* with new bellwether cases that are actually representative of a significant portion of the cases in this MDL. Specifically, the Court would identify, with input from the parties, four new bellwether trial pool cases—two involving the PerFix Plug and two involving the 3DMax. By keeping the same products as in *Stinson* and *Bryan*, there would be no need for additional generic discovery (or to disrupt generic discovery in progress). The parties

[2] Mr. Stinson first reported that he was seeking further treatment for groin issues in September 2022 and he did not undergo surgery until eight months later. Further, the parties have not yet begun the additional discovery required due to Mr. Stinson's recent treatment.

would then conduct case-specific fact discovery in those cases and the Court would select two—one involving each device—for trial. The other two cases would serve as replacements, in the event of summary judgment, dismissal, or some other reason why a trial set case would need to be replaced. While this process would push the schedule back, there is no guarantee that the current schedule will hold (given Mr. Stinson's and Mr. Bryan's ongoing medical developments). Additionally, the process would not impose a significant amount of additional work beyond that which will already be required to get *Stinson* and *Bryan* ready for trial and it would result in fairer trials and verdicts that would inform the parties and the Court about the overall strengths and potential values of a large swath of cases in this MDL, something not possible with trials of *Stinson* and *Bryan*.

## II. PROCEDURAL BACKGROUND

On November 20, 2018, the Court issued Case Management Order ("CMO") No. 10, which outlined the bellwether selection process. CMO No. 10, ECF No. 62. Pursuant to CMO No. 10, each side was to identify six "Representative Plaintiff candidates" to be included in the Bellwether Discovery Pool that fed into the Bellwether Trial Pool. *Id*. at 1.

> The Court will review the twelve Discovery Pool Plaintiffs selected by the Parties to ensure that they represent a sample of the cases currently pending in this MDL and are consistent with the guidelines set by the Court. The Court may in its sole discretion substitute any case on a Party's list with another case of its choosing and may request input from the Parties in doing so.

*Id.* at 2. Among the guidelines set by the Court were that cases should not involve more than one type of device or claims against manufacturers other than Bard, and should include a mix of ventral and inguinal products. CMO No. 10 also included provisions for the replacement of cases and to "otherwise adjust the balance of selections or the terms of this CMO to ensure the integrity of the bellwether process." *Id*. at 2 & 3. "This Order may be modified or amended for

good cause shown, after appropriate notice and opportunity to be heard is provided to the affected parties, when the Court believes the interest of justice requires modification." *Id.* at 3.

On January 31, 2019, the parties identified twelve total cases, including *Stinson*, *Miller*, and *Bryan*, for the Bellwether Discovery Pool. As expected, these cases involved one Bard product each, included both ventral and inguinal products, and did not include claims against other manufacturers. On July 12, 2019, in accordance with CMO No. 10, the parties collectively identified six of these cases, not including *Bryan*, for the Bellwether Trial Pool. The products at issue in the Bellwether Discovery Pool and Bellwether Trial Pool—Ventralight ST, Ventralex, PerFix Plug, and 3DMax—dictated the focus of generic fact and expert discovery.[3] On January 13, 2020, each side filed its respective briefs on why its three cases were most representative and should be selected for trial. *See* ECF Nos. 298 & 299.

At the January 13, 2020, CMC, the Court determined that it would select a fourth bellwether case to make the process fairer (by ensuring that each side was able to select an equal number of bellwether cases for trial). *See* 1/13/2020 Status Conf. Tr., ECF No. 304, at 63:1-64:13; *see also* 11/21/2022 Status Conf. Tr., ECF No. 696, at 13:18-20. On January 24, 2020, the Court selected *Johns*, *Milanesi*, *Stinson*, and an unidentified fourth case (to be picked by Bard) as the bellwether cases to be tried in this MDL. CMO No. 25, ECF No. 318, at 4. Bard proposed *Miller*, which involved the 3DMax and fairly typical claims, as the fourth bellwether case on February 12, 2020. *See* Def.'s Request to Schedule and Select the Fourth Bellwether Trial, ECF No. 343, at 2.

[3] For example, the Bard Mesh device now at issue in *Stinson* was not discussed by any of the experts designated by the plaintiffs in the Bellwether Trial Pool cases.

On February 4, 2021, the PSC and Bard raised dueling objections to *Miller* and *Stinson*, respectively, as bellwether trial cases. *See* 2/4/2021 CMC Tr., ECF No. 477, at 20:25-21:11 & 22:12-15. The Court noted that it wanted to ensure that the bellwether cases "inform both sides when it comes to what we're doing with the rest of them" and that if there was "a general feeling on one side that [a] case isn't representative, then it could have a way of impeding negotiations later." *Id*. at 23:14-18. The Court instructed the parties to file their objections to *Stinson* and *Miller*, focusing on whether the cases were representative and would help determine an appropriate settlement. *Id*. at 26:12-16. The parties filed their briefing on February 23, 2021. *See* ECF Nos. 483 & 484.

In their briefing, both parties emphasized the importance of selecting cases with common claims and injuries that were representative of a large number of cases in the MDL. *See, e.g.*, Def.'s Obj. to *Stinson* as the Third Bellwether Trial for Lack of Representativeness, ECF No. 484, at 3 ("Bard recommends selecting a third bellwether trial case that is more representative of the claims and purported injuries at issue in a broader range of cases in the MDL."); PSC's Brief on the Selection of the Fourth Bellwether Trial Case, ECF No. 483, at 8 (arguing that *Stinson* did not involve any unique questions that would render his case non-representative because his alleged injuries were common with PerFix Plug implants). At that time, there was no indication that *Stinson* would involve claims as to the Bard Mesh, that he would have an additional surgery before trial, or that his eventual surgery would involve the removal of a testicle, drastically changing the nature of the case. *See, e.g.*, Pl.'s Opp'n to Bard's Mot. for Summ. J., *Stinson* ECF No. 124, at 54 n.8 ("Mr. Stinson is not pursuing claims in this case for recovery of damages caused by Defendant's Bard Mesh device.").

After reviewing the parties' briefing, on June 10, 2021, the Court selected *Stinson* and *Miller* as the third and fourth bellwether cases, respectively. CMO No. 25-A, ECF No. 514, at 1. Bard was forced to replace *Miller* as its trial pick when Mr. Miller terminated his relationship with his counsel, a member of the PSC. On December 28, 2021, having no other 3DMax case remaining in the Bellwether Trial Pool, Bard proposed *Bryan* as a substitute, noting that it involved the same device as *Miller* and that his alleged injury, pain, was common to a vast majority (81.2%) of claimants in the MDL; the lack of change in *Bryan*'s medical status was expressly part of Bard's proposal.

Over the PSC's objection, the Court subsequently selected *Bryan* as the replacement for *Miller*; it set *Stinson* for trial on February 23, 2023, and *Bryan* for trial on May 15, 2023. *See* CMO No. 35, ECF No. 35, at 1. Since then, the Court has rescheduled both trials multiple times, due to the plaintiffs' ongoing medical issues. *See, e.g.*, CMO No. 37-A, ECF No. 148 (postponing the *Stinson* trial to May 15, 2023); CMO No. 42, ECF No. 707 (postponing the *Stinson* trial to October 16, 2023); 1/31/23 CMC Transcript, ECF No. 703, at 20 (postponing the *Bryan* trial to January 29, 2024); 2/8/23 Email, **Exhibit 1**.

## III. MATERIAL CHANGES TO THE FACTS OF *STINSON*

Almost three years after being identified as a Bellwether Trial Pool case and with no on-going care for his groin pain, in September 2022, Mr. Stinson sought to schedule an appointment to see a new doctor to evaluate his groin pain and the possibility of further surgery. On November 4, 2022, Mr. Stinson met with Dr. Dylan Jacobus, a new treating surgeon, who recommended a diagnostic and therapeutic right groin nerve injection. November 4, 2022 Medical Records, **Exhibit 2**. On November 8, 2022, the PSC informed Bard that Mr. Stinson planned to return to his explanting surgeon, Dr. Radke, for a second opinion on possible surgery.

Because Dr. Radke was retiring, however, Mr. Stinson met with a second new surgeon, Dr. Brittany Misercola, on November 16, 2022. Dr. Misercola concluded that Mr. Stinson's symptoms appeared "predominantly neuropathic" and recommended symptom management. November 16, 2022 Medical Records, **Exhibit 3**.

On January 31, 2023, the PSC reported that Mr. Stinson had tried conservative medication treatment that failed to provide him permanent relief. Additionally, Mr. Stinson had undergone a nerve injection from Dr. Jacobus and had a second nerve injection scheduled for February 15, 2023. The expectation was that the injections would not resolve Mr. Stinson's pain and that Mr. Stinson would have a neurectomy—a limited surgery—in March 2023. Mr. Stinson received a second nerve injection on February 15, 2023. On March 7, 2023, the PSC again reported to the Court that a neurectomy was at issue. 3/7/23 CMC Transcript, ECF No. 703, at 5 ("[T]he doctor has indicated that a neurectomy is going to be the next procedure.").

On March 17, 2023, Dr. Jacobus recommended a third injection and informed Mr. Stinson that if the third injection did not provide permanent relief, Dr. Jacobus would perform a right groin exploration with possible neurectomy (i.e., the severing or removal of a nerve) and possible orchiectomy (i.e., removal of a testicle). March 17, 2023 Medical Records, **Exhibit 4**. Mr. Stinson had a third nerve injection on March 20, 2023, which he reported did not provide him lasting relief.

On April 6, 2023, the PSC notified Bard that Mr. Stinson had a right groin exploration scheduled for May 10, 2023. The PSC noted that the surgery could involve not only a neurectomy, but also the removal of Mr. Stinson's Bard Mesh; the PSC made no mention that the surgery could also involve the removal of Mr. Stinson's testicle. On May 10, 2023, eight months after first reporting that he was seeking further treatment, Mr. Stinson underwent a right groin

exploration. May 10, 2023 Operative Note, **Exhibit 5**. During the operation, Dr. Jacobus discovered that Mr. Stinson's Bard Mesh was wrapped along the length of the spermatic cord, such that it could not be removed without removing Mr. Stinson's right testicle and his spermatic cord. *Id*. at 2. Dr. Jacobus removed both, along with Mr. Stinson's Bard Mesh. *Id*. at 1-2. Plaintiff has not yet amended his Short Form Complaint, Plaintiff Profile Form, or Plaintiff Fact Sheet to reflect this operation or any claims related to the explanted Bard Mesh.

## IV. MATERIAL CHANGES TO THE FACTS OF *BRYAN*

On January 11, 2023 (more than five years after his last appointment with a physician concerning groin pain), as the parties were negotiating a pretrial schedule for *Bryan*, Mr. Bryan met with Dr. Jeffrey Rose with a chief complaint of groin pain. January 11, 2023 Medical Record, **Exhibit 6**. Dr. Rose reported that there was no sign of hernia recurrence and recommended an ultrasound to determine the cause of Mr. Bryan's pain. *Id*. Dr. Rose noted that a left groin exploration might be required to ligate Mr. Bryan's left ilioinguinal nerve. *Id*. A subsequent ultrasound revealed no hernia or other abnormality. January 30, 2023 Ultrasound Record, **Exhibit 7**. On February 8, 2023, Dr. Rose informed Mr. Bryan that there was no obvious source for his symptoms and discussed various treatment options with Mr. Bryan, including pain management, physical therapy, and groin exploration with nerve ligation. February 8, 2023 Medical Record, **Exhibit 8**. Mr. Bryan elected to have surgery, and Dr. Rose scheduled a left groin exploration with ilioinguinal nerve ligation, *i.e.*, a neurectomy. *Id*. After receiving a pathology preservation letter from the PSC, however, the hospital cancelled the surgery and referred Mr. Bryan to a different hospital. Bard and the Court did not learn about any of this until after the fact. It is now expected that Mr. Bryan will undergo an additional surgery that could involve the removal of one of his testicles. *See* 4/11/2023 CMC Tr., ECF No.

721, at 3 ("Mr. Bryan has been complaining of pain in his testicles, burning pain in his testicles, essentially from his deposition.").

## V. ARGUMENT

### A. To Produce Meaningful Information, Bellwether Cases Must Be Representative Of The MDL

The purpose of a bellwether case "is to 'enhance and accelerate both the MDL process itself and the global resolutions that often emerge from that process.'" *In re Zimmer M/L Taper Hip Prosthesis*, MDL No. 2859, 2022 U.S. Dist. LEXIS 11866, *32 (S.D.N.Y. Jan. 21, 2022) (quoting Fallon, et al., *Bellwether Trials in Multidistrict Litigation*, 82 Tul. L. Rev. 2323, 2325 (2008)). "In other words, bellwether cases should be 'representative' of the overarching issues within the overall MDL to aid the development of the parties' disputes and put a value on the litigation." *Id*. (citing *In re FEMA Trailer Formaldehyde Prod. Liab. Litig*., No. 092967, 2009 WL 3418128, at *3 (E.D. La. Oct. 14, 2009), *aff'd sub nom*. *In re FEMA Trailer Formaldehyde Prod. Liab. Litig*., 628 F.3d 157 (5th Cir. 2010) (finding one of "the principle goals of the bellwether process" is to select a plaintiff or plaintiffs "who can truly be representative of the whole mass of plaintiffs in the MDL")). As such, the ideal bellwether case is one that presents issues representative of those *commonly asserted* in the broader range of cases in the MDL. *See In re E. I. Du Pont Nemours & Co. C-8 Personal Injury Litig*., 204 F. Supp. 3d 962, 968 (S.D. Ohio 2016) (quoting The Manual for Complex Litigation § 22.315 (2004)).

Since the beginning of the bellwether selection process in this MDL, the Court has recognized the importance of selecting bellwether cases that will provide meaningful information to the parties and will aid in the resolution of this litigation. *See, e.g*., 2/4/2021 CMC Tr., ECF No. 477, at 23:14-15 ("COURT: I do want these [bellwether] cases to inform both sides when it comes to what we're doing with the rest of them."), 26:6-11 (noting that the bellwether selection

process is about "trying to get some cases where you can evaluate your positions and see where the rest of them are going to go") & 24:10-11 (noting that the resolution of each bellwether case "should mean something"). Starting with CMO No. 10, there has been a possibility of replacing trial cases "or otherwise adjust[ing] the balance of selections or the terms of this CMO to ensure the integrity of the bellwether process." The Court has done just that a number of times, including the replacement of *Miller* with *Bryan*, a case that was not part of the Bellwether Trial Pool.

The parties have similarly agreed on the importance of selecting cases that are representative of the facts and issues common to a large number of cases in the MDL. *See, e.g.*, PSC's Proposal for the Selection of Initial Bellwether Trial Cases, ECF No. 298, at 2 ("[C]ases with the most representative issues (and facts) that can be applied to other cases (ideally a lot of other cases) should be selected as being most instructive to the litigation as a whole."); Defs.' Brief Regarding Bellwether Trial Case Selection, ECF No. 299, at 1 ("The parties selected the original twelve cases for the Bellwether Discovery Pool with the intention that they would be representative of the cases in this MDL."). The parties also agree that cases that present unique issues should be excluded. *See, e.g.*, PSC's Proposal for the Selection of Initial Bellwether Trial Cases, ECF No. 298, at 1 ("[A]ny case possessing unique legal or factual issues should not be selected [for inclusion in the bellwether pool]."); Def.'s Further Obj. to *Stinson* for Lack of Representativeness and in Support of *Miller* as to Representativeness, ECF No. 492, at 5 ("Representative cases address as many common issues and facts as possible and are not unique cases that make up less than 1% of MDL plaintiffs, like *Stinson*."). Trying bellwether cases that will provide meaningful information to the parties and the Court about a large swath of cases is imperative for the bellwether process to function as intended.

### B. *Stinson* And *Bryan* Are No Longer Representative Of Cases In The MDL

The MDL now consists of approximately 19,862 cases. The vast majority of cases (71%) involve a single device, the four most common of which are: (1) Ventralight ST (16%); (2) PerFix Plug (15%); (3) Ventralex (14%); and (4) 3DMax (7%). Together, cases involving these four devices make up more than one-half of the total cases in this MDL. In addition to covering common products used for both ventral and inguinal repair, as the time they were selected for trial, *Johns*, *Milanesi*, *Stinson*, *Miller/Bryan*, involved common injuries such as adhesions, recurrence, bowel obstruction, and groin pain.[4] They also involved only one Bard device per case.[5]

The Court and parties have consistently agreed that it is essential to have bellwether trial cases that have the most representative facts and issues, including alleged injuries, that can be applied to other cases to enable the parties and the Court to evaluate the strengths and potential values of a majority of cases in this MDL. Trying a case with a unique set of facts will not serve this purpose. In other words, if a PerFix Plug or 3DMax case is tried, but its facts are so unique that the verdict reached in that case would not tell the parties anything meaningful about the other cases in the MDL, then the trial will only serve to waste the parties' and the Court's time, regardless of how much work has been done to date. In the end, the work already done (and the future work) will be for naught.

#### 1. *Stinson* Is No Longer Representative

At the time *Stinson* was selected as a bellwether trial case, the case involved facts and

[4] The most commonly alleged injury in this MDL is pain (87%). Recurrence is the second most commonly alleged injury (67%) and adhesions is the third (57%). Contrarily, loss of a testicle is alleged in only 1% of cases. Bard is unaware of any case in which a plaintiff has alleged removal of his spermatic cord.

[5] Only 10% of cases involve a second device.

issues relatively common in the MDL.[6] Specifically, Mr. Stinson was implanted with a PerFix Plug in August 2015 to repair a right inguinal hernia. After the implant, Mr. Stinson allegedly developed significant post-operative pain, which was treated with nerve blocks and steroid injections in 2016, without permanent relief. In June 2017, Mr. Stinson had his PerFix Plug removed and a Bard Mesh placed to prevent a recurrence. Mr. Stinson's primary complaints were pain, excessive fibrosis, and chronic inflammation. The Bard Mesh remained implanted and there was no claim or evidence that the Bard Mesh had caused Mr. Stinson injury.

Over the course of the last eight months, the facts of *Stinson* have materially changed. Most significantly, on May 10, 2023, Mr. Stinson underwent surgery that resulted in the removal of his right testicle, his spermatic cord, and his Bard Mesh. These additional injuries have changed this case from one involving a relatively straightforward set of facts that were common across the MDL (i.e., a single device and pain) to one that is far more complex and involves allegations of several heightened and uncommon injuries. A jury evaluating liability and damages will undoubtedly view the new alleged injuries as being much more severe than a single explant with resulting pain, resulting in an increased risk of liability and damage award. Mr. Stinson's new injuries have the very real potential of impacting a jury award based on complications that are not common in the MDL, negating the applicability of that award to other cases in the MDL. Indeed, unlike Mr. Stinson's original alleged injuries, loss of a testicle is alleged in a small fraction of cases and Bard is not aware of any case in which the plaintiff has

[6] Bard previously objected to *Stinson* as a bellwether trial case on the grounds that Mr. Stinson had a second Bard device implanted and his allegations of various complications made his case not representative. *See* Def.'s Obj. to *Stinson* as the Third Bellwether Trial For Lack of Representativeness, ECF No. 484. The PSC subsequently clarified that Mr. Stinson's primary complaints were pain, chronic inflammation, and excessive fibrosis that he claimed resulted from the PerFix Plug. *See* PSC's Reply Brief on the Selection of the Fourth Bellwether Trial Case, ECF No. 493, at 3.

alleged loss of spermatic cord. As such, any verdict reached in *Stinson* would not be informative as to the strengths or potential values of a broad range of cases. Rather, the verdict would be limited to the specific facts of *Stinson*.

The removal of Mr. Stinson's Bard Mesh further diminishes the representativeness of his case. According to Dr. Jacobus's operative report, the Bard Mesh was wrapped along the length of Mr. Stinson's spermatic cord such that the Bard Mesh could not be explanted unless Mr. Stinson's testicle and spermatic cord were removed. As such, the jury will not only be evaluating evidence related to Mr. Stinson's PerFix Plug, it will also hear evidence and argument that a second Bard mesh device had to be explanted and that it was that device that necessitated the removal of Mr. Stinson's spermatic cord and right testicle.

While the PSC has represented that Mr. Stinson will not be making a claim for the Bard Mesh, they do intend to present evidence about the 2023 surgery and argue that the "reaction" to the Bard Mesh supports the claim as to the PerFix Plug. This is sophistry. For the jury, it will be inevitable to link the removal of Mr. Stinson's testicle and spermatic cord to the Bard Mesh, regardless of what appears on the verdict form. The complicated case-specific facts and now significant and unrepresentative injuries at issue in this case will undoubtedly influence the jury's determinations of liability and damages. Because the case is now not representative of the cases across the MDL, any jury award would do nothing to inform the Court or the parties about the value of other cases in the MDL.

In arguing that *Stinson* was representative and should be selected as a bellwether trial case, the PSC relied heavily on Mr. Stinson's allegations of pain and the commonality of that injury across cases in the MDL. *See, e.g.*, PSC's Proposal for the Selection of Initial Bellwether Trial Cases, ECF No. 298, at 5 (arguing that *Stinson* was representative because the alleged

injuries were "very common" with the PerFix Plug); PSC's Reply Brief on the Selection of the Fourth Bellwether Trial Case, ECF No. 493, at 3 (arguing that Mr. Stinson's primary complaints were pain, excessive fibrosis, and chronic inflammation, "which are typical to most plaintiffs in this MDL") & 8 (arguing that because Mr. Stinson's injuries were highly representative and damages a jury would award for them "will be very instructive as to the values that should be assigned to similar case[s]").

*Stinson*, however, is a different case now—it has very different facts and heightened alleged injuries that are uncommon in the MDL. As such, *Stinson* is no longer an appropriate bellwether trial case. *See In re E.I. du Pont de Nemours*, 529 F. Supp. 3d at 740 ("Bellwether plaintiffs are purposefully selected to exclude the most severely injured plaintiffs because it would frustrate the bellwether procedure's purpose. That is, the need to try multiple bellwether cases to facilitate settlement of all cases in an important component of the handling an MDL.").

**2. *Bryan* Is No Longer Representative**

Mr. Bryan was implanted with a 3DMax in November 2012 to treat a hernia. In or around July 2015, Mr. Bryan began experiencing pain in his testicle. Mr. Bryan's 3DMax was partially removed in October 2017. At the time Bard identified *Bryan* as its second bellwether trial case—as a replacement for a representative 3DMax case that was dismissed because of a falling out between the plaintiff and his PSC counsel—the only current complaint was pain. In its letter proposing *Bryan* as the fourth bellwether case, Bard explained that *Bryan* was representative because Mr. Bryan was implanted with a 3DMax, the second most common inguinal device and his alleged injury, pain, was common to more than 81% of claimants in the MDL. Additionally, Bard noted that its proposal assumed that Mr. Bryan had not experienced a material change in this health or medical history since his deposition, including, but not limited

to, having additional surgeries. Because *Bryan* was not part of the Bellwether Trial Pool and Bard was forced to go back to the Bellwether Discovery Pool to find a 3DMax case to replace *Miller*, the medical information on *Bryan* was even more out-of-date. Bard reserved its right to propose a different case if such material changes occurred. And they have, as Bard and the Court learned much later.

In March 2023, Bard and the Court learned that in January 2023, after five-and-a-half years of not seeking treatment for groin issues, Mr. Bryan met with a surgeon, Dr. Rose, who informed Mr. Bryan that he may require nerve ligation. While it is hard to assess whether the nearing trial date had anything to do with Mr. Bryan seeking treatment for groin pain for the first time in more than five years, these ongoing developments of Mr. Bryan's medical course make his case a moving target. Indeed, it is impossible to know exactly what Mr. Bryan's alleged injuries will be and if those injuries will be representative of a broad range of cases in the MDL. Bard anticipates that, at the very least, Mr. Bryan will undergo an additional surgery.

Additionally, there has been suggestion that Mr. Bryan may lose one of his testicles. As previously noted, the loss of a testicle is alleged in only 1% of cases, but is likely to have a significant impact on a jury's evaluation of a case. Had these circumstances been present at the time Bard proposed *Bryan* as the fourth bellwether trial, Bard would have chosen a different case. *See* 4/11/2023 CMC Tr., ECF No. 721, at 4:14-22 (noting that *Bryan* was beginning to look less representative and that if Mr. Bryan had been seeking treatment for groin pain at the time was evaluating cases for bellwether trial selection, Bard would not have picked his case). It would not have even identified *Bryan* for the Bellwether Discovery Pool in January 2019. Under these circumstances, it would be fundamentally unfair to force Bard to stick with its back-up choice for its second bellwether trial case.

### C. Selecting New Bellwether Cases Will Not Impose A Significant Amount of Additional Work Beyond That Which *Stinson* And *Bryan* Require And Would Serve The Goals of Bellwether Cases

Because *Stinson* and *Bryan* no longer involve facts and issues common to a broad range of cases in the MDL, the best way to ensure the bellwether process serves its intended purpose is to remove *Stinson* and *Bryan* as bellwether trial cases and select new cases to replace them. Bard recognizes that the parties and the Court have expended valuable time and resources preparing these cases for trial and that the Court has been working hard to issue opinions on the various motions filed. That effort is certainly appreciated by both sides. However, the significant changes to the facts and allegations, and the uncertainly regarding where both plaintiffs' medical course will end up, have made it such that these cases are no longer representative.

To continue moving forward with *Stinson* and *Bryan* simply because work has been done to prepare them for trial will, in the end, only frustrate the ultimate goals of resolution of the MDL. It will also waste the Court's and the parties' time and resources because a verdict in those cases would not serve any meaningful purpose. Selecting new cases that are actually representative of the overall MDL, on the other hand, would maintain the integrity of the bellwether process by ensuring that the verdicts reached in the remaining bellwether trial cases provide information that the parties and the Court can use to evaluate a broad range of cases. *See In re Welding Fume Prods. Liab. Litig*., No. 1:03-CV-17000, 2007 U.S. Dist. LEXIS 41681, *19 n.3 (N.D. Ohio June 6, 2007) ("[T]he purpose of a series of bellwether trials is to 'produce a sufficient number of representative verdicts' to 'enable the parties and the Court to determine the nature and strength of the claims, whether they can fairly be developed and litigated on a group basis, and what range of values the cases may have if resolution is attempted on a group basis.'") (quoting Manual for Complex Litigation Fourth §22.315 at 360 (2004)). As such,

selecting new cases would be in the interest of justice. *See* CMO No. 10, ECF No. 62, at 3.

Bard proposes that the parties each select two representative PerFix Plug cases and two representative 3DMax cases as potential bellwether trial cases. Because the new cases would involve the same devices at issue in *Stinson* and *Bryan*, no additional generic discovery would be required. The parties would complete case-specific discovery over the next few months and expert discovery shortly thereafter. *See* PSC's Brief on the Selection of the Fourth Bellwether Trial Case, ECF No. 344, at 3 (PSC agreeing that working up a handful of cases can be done "in short order"). At the close of case-specific discovery, one case involving each device would be selected as the bellwether trial cases, with the plaintiff pick being the third trial and the defense pick being the fourth trial, maintaining the balance of trials envisioned from the start. The other two cases would serve as replacements in the event one of the bellwether trial cases cannot be tried because of dismissal or another reason.

Although it might seem that selecting new cases at this juncture would impose a significant burden on the parties and the Court, it will not. As a result of Mr. Stinson's and Mr. Bryan's ongoing medical issues, the parties will already be required to conduct additional depositions, including those of the plaintiffs, multiple healthcare providers, and the parties' experts. *Bryan* has had no expert discovery or motions practice yet. In *Stinson*, multiple experts for each side will need to supplement their reports and get deposed. The parties in *Stinson* will also need to submit additional briefing, including motions *in limine* and Rule 702 motions. Notably, none of this work can even begin until the plaintiffs have completed and fully recovered from their treatment. And because the plaintiffs continue to receive additional treatment, it is unclear when that will be.

Contrarily, the parties could immediately begin identifying substitute cases and

proceeding to case-specific discovery. The timing of getting new cases ready for trial would not differ greatly from the current trial schedule, which is optimistic given what remains to be done and the uncertainty of the medical situations for these plaintiffs. The incremental increase in work and relatively short delay in trials would be worth it to have bellwether trials that actually serve their intended purpose.

## VI. CONCLUSION

For the reasons stated above, Bard respectfully requests that the Court find *Stinson* and *Bryan* not representative of the MDL and that it is in the interests of justice to replace them with cases that are more representative.

DATED: May 24, 2023

Respectfully Submitted,

*/s/ Eric L Alexander*

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*Liaison counsel for Defendants C. R. Bard, Inc. and Davol Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that on May 24, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of this electronic filing to all counsel of record.

*/s/ Eric L. Alexander*
Eric L. Alexander

# EXHIBIT 1

**Fierro, Corinne**

| | |
|---|---|
| **To:** | Ashlee Riner; Butler, David J.; Alexander, Eric L.; Brown, Michael K.; Moberg, Marilyn A.; Jacobson, Matthew D.; Kelsey Stokes; tobrien@levinlaw.com; ZZ-Cohen, Lori; Jeff Grand; ZZ-Kloss Jr., William D.; mlondon.douglasandlondon.com; jessees@gtlaw.com; ZZ-Merrell, Cliff |
| **Cc:** | OHSDdb_Sargus_Ch; Christin Werner |
| **Subject:** | RE: In Re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation; United States District Court Southern Division of Ohio Case no. 2:18-md-2846 |

**From:** Ashlee Riner <Ashlee_Riner@ohsd.uscourts.gov>
**Sent:** Wednesday, February 8, 2023 6:38 AM
**To:** Butler, David J. <dbutler@taftlaw.com>; Alexander, Eric L. <EAlexander@ReedSmith.com>; Brown, Michael K. <MKBrown@reedsmith.com>; Moberg, Marilyn A. <MMoberg@ReedSmith.com>; Jacobson, Matthew D. <MJacobson@ReedSmith.com>; Kelsey Stokes <kelsey_stokes@fleming-law.com>; tobrien@levinlaw.com; ZZ-Cohen, Lori <cohenl@gtlaw.com>; Jeff Grand <JGrand@seegerweiss.com>; ZZ-Kloss Jr., William D. <WDKlossjr@vorys.com>; mlondon.douglasandlondon.com <mlondon@douglasandlondon.com>; jessees@gtlaw.com; ZZ-Merrell, Cliff <merrellc@gtlaw.com>
**Cc:** OHSDdb_Sargus_Ch <Sargus_Chambers@ohsd.uscourts.gov>; Christin Werner <Christin_Werner@ohsd.uscourts.gov>
**Subject:** RE: In Re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation; United States District Court Southern Division of Ohio Case no. 2:18-md-2846

EXTERNAL E-MAIL - From Ashlee_Riner@ohsd.uscourts.gov

Good morning counsel,

January 29, 2024 is fine with Judge Sargus, and he asks that the parties submit a proposed scheduling order by **February 22, 2023**.

Best,
Ashlee

**Ashlee Riner**
Law Clerk to the Honorable Edmund A. Sargus, Jr.
U.S. District Court for the Southern District of Ohio
Joseph P. Kinneary U.S. Courthouse
85 Marconi Boulevard
Columbus, OH 43215
Telephone: (614) 719-3253

# EXHIBIT 2

Patient: STINSON, AARON A

MRN:1261850
FIN:364861484

# Office Notes

**Referring Physician -**
FUSCO DO, ANTHONY L

**Chief Complaint**
Right hernia

**Assessment/Plan**
Mr. Stinson is a 51-year-old gentleman with chronic right groin pain following to right inguinal open operations. I had a long conversation with him and his wife. We discussed the different treatment strategies. We also discussed the different diagnostic methods. Differential diagnosis for him includes ilioinguinal or iliohypogastric neuralgia, recurrent inguinal hernia, abdominal muscle strain, lumbar radiculopathy, or pain from his bladder outlet obstruction. Bladder outlet obstruction is thought to be less likely as the cause of his symptoms. This time I would like to proceed with a diagnostic and therapeutic right groin injection. We will plan to set this up in the near future coordinating this with the patient schedule. We did discuss the potential for MRIs, ilioinguinal or iliohypogastric neurectomy, or repeat repair of his right inguinal hernia. All his questions and concerns were addressed. We will contact him to schedule his injection.

**History of Present Illness**
Mr. Stinson is a 51-year-old gentleman who comes in today for recurrent right inguinal pain. He has a complicated history with regards to his right inguinal issues. He underwent an open right inguinal hernia repair in 2015. This time he was noted have a large direct defect and a large plug was placed. He had worsening right groin pain following this operation. For approximately 2 years he has struggled with worsening right groin pain. He then went and saw specialist in Portland. That time he went through a right groin exploration. The plug was removed. A another piece of mesh was placed. Following this operation his symptoms greatly improved. He continued to have some mild right groin pain but was a significant improvement from where he was. There was no note during that operative report if he underwent an ilioinguinal neurectomy. Since 2017 he has had progressively worsening right groin pain. Some days will be worse than others. Tells me that he usually has a constant 3 to 4/10 stabbing pain in his right groin. This will worsen with activity. He does perform a strenuous job and is a caretaker working for a company that manages 38 properties. He is able to work through the pain during the day, but this significantly affects his life when he gets home. He did undergo recent CT imaging which showed a recurrent right inguinal hernia. This looks like a small indirect hernia on the right and a possible small indirect hernia on the left. There is also some concern for bladder outlet obstruction related to an enlarged prostate.

He does have urinary symptoms. He tells me that he will have urinary urgency and hesitancy. He will often have dribbling after he has completed his voiding. He has a difficult time starting his stream is. Sometimes he has to apply abdominal pressure to empty his bladder. He never feels like he completely empties. This could be contributing to some of his inguinal pain.

**Review of Systems**
**Constitutional:** Denies fever
**Skin:** Denies rash
**Eye:** Denies eye pain
**ENMT:** Denies sore throat and nasal congestion
**Respiratory:** Denies shortness of breath and cough
**Gastrointestinal:** Endorses right groin pain
**Cardiovascular:** Denies chest pain and syncope
**Genitourinary:** Denies dysuria
**Musculoskeletal:** Denies back pain and extremity pain
**Neurologic:** Denies headaches, confusion, and weakness

Constipation
Ganglion cyst of wrist
History of hernia repair
Lyme disease
Panic disorder
Right groin pain
Urinary urgency

Historical
No qualifying data

**Procedure/Surgical History**
- IH (inguinal hernia) (08/05/2015)
- Appendectomy;
- Arthroscopy
- Foot laceration

**Medications**
Medications Administered in Office
No active medications

Home Medications / Unchanged:
diclofenac topical (diclofenac 1% topical gel), 2 gm, Topical, FOUR TIMES DAILY
DULoxetine (DULoxetine 60 mg oral delayed release capsule), 60 mg = 1 CAP, Oral, DAILY ,# 30CAP
hydrOXYzine (hydrOXYzine hydrochloride 25 mg oral tablet), 25 mg = 1 TAB, Oral, DAILY As Needed For as needed for anxiety,# 10TAB
tamsulosin (Flomax 0.4 mg oral capsule), 0.4 mg = 1 CAP, Oral, DAILY ,# 30CAP

**Allergies**
NKA
No Known Medication Allergies

**Social History**
Abuse/Neglect
Feels unsafe at home: No. Safe place to go: Yes. Injuries/Abuse/Neglect in household: No., 07/29/2021
Alcohol
Use: Denies., 09/30/2022
Electronic Cigarette/Vaping
Never, 09/30/2022
Employment/School
Status: Employed. Work/School description: Caretaker/maintenance for Isle au haut homes., 05/20/2020
Home/Environment
Lives with Spouse. Spouse Name: Gail Stinson. Marital Status of Parents: Married. Living situation: Home/Independent., 07/29/2021
Nutrition/Health
Diet: Regular., 07/29/2021
Substance Use History

# EXHIBIT 3

## 11/16/2022 - Office Visit in MMP GENERAL SURGERY (continued)

**Medication List (continued)**

Authorized by: Misercola, Brittany, MD
Start date: 11/16/2022
Refill: 3 refills by 11/16/2023

Ordered on: 11/16/2022
Quantity: 60 Capsule

**Stopped in Visit**

None

**Progress Notes**

**Progress Notes**

**Stilkey, Brianna N at 11/16/2022 1336**

**Concerns for Provider:** Yes - Patient taking anxiety medication 2 hours prior to doctor appointment, unsure of the name of medication. Patient believes to have had hernia for years, unsure how long. Stairs and physical activity increases the pain. Job does require physical activity. Denies N/V/D and fever. Constipation bu patient taking medication for it.

**Action Taken:**

Electronically signed by Stilkey, Brianna N at 11/16/22 1524

**Misercola, Brittany, MD at 11/16/2022 1344**

### Maine Medical Partners Surgical Care History and Physical

| | |
|---|---|
| **Patient Name** | STINSON,AARON |
| **DOB** | 1/27/1971 |
| **MRN** | E2862877 |
| **Visit Date** | 11/16/2022 |

**Assessment/Plan:**

1. 51 year old male with right inguinal pain, s/p right inguinal hernia repair by Dr. Radke 6/20/2017.
2. Continue non-operative management.
3. Consider nerve block vs neurectomy- higher risk with previous scar tissue. Favor ablation with block.
4. Start Lyrica
5. CT scan results requested
6. Follow up with PCP, recommend urology consult, colonoscopy
7. Phone follow up in 1 month

**Chief Complaint:** Right inguinal pain

**History of Present Illness:**

**11/16/2022 - Office Visit in MMP GENERAL SURGERY (continued)**

**Progress Notes (continued)**

51 year old male patient with history of right inguinal hernia repair by Dr. Radke 6/20/2017 who presents with progressive right inguinal pain.

Mr. Stinson reports a history of "cribbipling pain" prior to right inguinal hernia revision in 2017. Post op from right inguinal hernia his pain progressively improved. Over the summer he noticed increasing right inguinal burning, stabbing pain. Pain is worse with activity, certain position changes or when walking up/down stairs.
He previously took Gabapentin. Gabapentin helped with the pain but caused stomach discomfort.
He has excepted job promotion and is worried that ongoing symptoms will worsen.

After surgery he was left with a right swollen testicle. He reports trouble with urination. He reports needing to strain and push to get urine out, also has leaking.

He feels the sensation of a bulge in his right groin.
Bowels are constipated.

**Review of Systems:**
Gen: No fevers, chills, night sweats, fatigue, malaise
Ophthalmic: No decreased vision, blurry vision, eye pain
ENT: No change to hearing, smell, or taste; no difficulty swallowing
Heme: No easy bruising or prolonged bleeding
Endocrine: No unexpected weight gain or loss, no heat/cold intolerance
Respiratory: No shortness of breath, cough, or wheeze
Cardiac: No chest pain, palpitations, or edema
GI: Right sided inguinal pain
GU: Difficult to maintain urinary flow, dripping
Musculoskeletal: No joint pain or swelling, no muscle pain
Neuro: No vertigo, headaches, or syncope
Derm: No rashes, hives, or welts

**Allergies:** No Known Allergies

**Medications:**
**Current Outpatient Medications on File Prior to Visit**

| Medication | Sig | Dispense | Refill |
|---|---|---|---|
| • lidocaine 5 % OINT | Apply topically as needed | Not taking | |
| • ibuprofen 200 MG TABS | Take 400 mg by mouth every 6 hours as needed for Pain Take with food. | PRN | |
| • diclofenac 75 MG TBEC | Take 75 mg by mouth 2 times daily | Not taking | |
| • venlafaxine 75 MG TABS | Take 75 mg by mouth daily | Not taking | |
| • nortriptyline 25 MG CAPS | Take 1 tab at bedtime (Patient not taking: Reported on 11/16/2022) | Not taking | 3 |
| • gabapentin 300 MG CAPS | Take 600 mg by mouth 3 times daily | Not taking | |

(Patient not taking: Reported on 11/16/2022)

Not taking gabapentin. Helped with pain, caused stomach upset.

Taking Duloxetine 60mgs

**PMHx:**
**Past Medical History:**

| Diagnosis | Date |
|---|---|
| • Acute urinary retention<br>*prostate issues* | |
| • Depression | |
| • Enlarged testicle<br>*right* | 2015 |
| • Hx of degenerative disc disease | |
| • Inguinal hernia | |
| • Inguinodynia, right | 8/15/2016 |
| • Knee pain<br>*left* | |
| • Lyme disease | |
| • Neuropathic pain | |
| • Osteoarthritis | |
| • Tick bite | |

Left knee pain

**PSHx:**
**Past Surgical History:**

| Procedure | Laterality | Date |
|---|---|---|
| • HX APPENDECTOMY | | |
| • HX INGUINAL HERNIA REPAIR<br>*w/mesh* | Right | 08/05/2015 |
| • HX KNEE SURGERY | Left | 1996 |
| • HX SKIN GRAFT<br>*left foot* | Left | |

**FamHx:**
Aunt and uncle with lung cancer
Aunts have Crohn's

**Social History**

Tobacco Use

| | |
|---|---|
| • Smoking status: | Never |
| • Smokeless tobacco: | No |
| Types: | Chew/1 can ever 2 days |

Substance Use Topics

| | |
|---|---|
| • Alcohol use: | No |
| Alcohol/week: | 0.0 standard drinks |

**11/16/2022 - Office Visit in MMP GENERAL SURGERY (continued)**

**Progress Notes (continued)**

Other: Marijuana 1/2 joint a day

From Dearisle, works as care taker on an island

**Relevant Imaging:**
1. CT scan completed at Blue Hill. Images unavailable, and requested

**MOST RECENT VITAL SIGNS**
BP 143/75 (BP Site: Left arm, Patient Position: Sitting, Cuff Size: Large Adult) | Pulse 72 | Temp 36.8 °C (98.3 °F) (Temporal) | Wt 111.1 kg (245 lb) | BMI 36.29 kg/m²

**Physical Exam**
**General:** AAO, no distress, well appearing
**HEENT:** Normocephalic, atraumatic, no scleral icterus
**Cardiac:** Regular rate and rhythm to pulse check
**Chest:** Nonlabored on room air
**Abdomen:** Soft, nondistended, nontender to palpation. Well healed surgical incision, no obvious mass/buldge Well healed midline incision
**Neurological:** Grossly normal, interacts appropriately
**Musculoskeletal:** Grossly normal, no deformities
**Derm:** Grossly normal, no rashes, no discoloration or jaundice

Lisa M Decesare, NP
**Date:** 11/16/2022 **Time:** 1:44 PM

I have seen and examined the patient with the resident/APP, and agree with the above except as noted below:

Patient with chronic right groin pain after prior hernia repair x 2. No bulge on exam, though ?seen on CT. At this point his symptoms seem predominantly neuropathic - would try symptom management rather than repeat exploration, especially as symptoms were manageable while on gabapentin but he had GI intolerance to the medication. Will try lyrica, if no relief likely try pain management injections and possible nerve ablation. Also will obtain CT imaging in the meantime. F/u telephone ~6 weeks.

Given complexity of patient history and discussion of the above, 57 minutes was spent with this patient and his wife.

Brittany Misercola, MD

Electronically signed by Misercola, Brittany, MD at 11/16/22 1524

**Other Orders**

# EXHIBIT 4

Patient: STINSON, AARON A

MRN:1261850
FIN:379491798

## *Office Notes*

# Allergies

NKA
No Known Medication Allergies

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At Northern Light Health we are committed to making healthcare work for you. Part of that is making your care more accessible using innovations through technology. We now offer the ability to securely connect some of the health management apps you may use (i.e. fitness trackers, dietary trackers, etc.) to your electronic health record. Visit myNorthernLightHealth.org for more information about our patient portal, available wellness applications, and instructions on how to connect/authenticate available wellness applications.

You may receive a survey from Press Ganey by mail or email asking you about your experience receiving care at Northern Light Health. Your feedback matters. Please complete the survey to share your experience with us!

*Electronically Signed By: BROBERG , LISA*
*Date/Time Signed: 03/17/2023 02:12 PM*

---

Document Type: General Surgery Office Note

Verified By: FRALEY MD,LARRY M (3/20/2023 14:44 EDT); JACOBUS MD,DYLAN P (3/17/2023 14:15 EDT)

Service Date: 3/17/2023 14:13 EDT

**Addendum by FRALEY MD, LARRY M on March 20, 2023 14:18:02 EDT**
I agree with above. No change since above visit.
Patient states that the last block only lasted 1 hour.
Plan third Ilioinguinal/ Iliohypogastric Block.

---

*Electronically Signed By: FRALEY MD, LARRY M*
*Date/Time Signed: 03/20/2023 02:44 PM*

**Primary Care Physician**
**Primary Care Physician -**
FUSCO DO, ANTHONY L

**Chief Complaint**
Discuss possible surgery

**Assessment/Plan**
Mr. Stinson is a 52-year-old gentleman with chronic groin pain. He is had 2 inguinal surgeries in the past. His most recent inguinal surgery was in 2017. He had maybe 1 year to 18 months of relief of his groin pain following the operation in 2017. He is tried gabapentin and Lyrica. These have had limited relief. He is also had limited relief with injections. At this time he was scheduled for his 3rd groin injection next week. I would like for him to complete this to make sure that the groin injections will

**Problem List/Past Medical History**
Ongoing
- Anxiety
- Arthritis of left knee
- Benign prostate hyperplasia
- Constipation
- Ganglion cyst of wrist
- History of hernia repair
- Lyme disease
- Panic disorder
- Right groin pain
- Urinary urgency

Historical
- No qualifying data

## Office Notes

not resolve his groin pain. I am also going to send a prescription for 100 mg of gabapentin twice daily. I will call him after his groin injection to see how he is feeling. If he has no relief then we will plan to schedule a right groin exploration with possible neurectomy and possible orchiectomy. All his questions and concerns were addressed. He understands. Wishes to proceed with the above plan.

**History of Present Illness**
Aaron returns to clinic today for follow-up of his right groin pain. He is no longer taking gabapentin. He is not taking Lyrica. He has been working full-time but has significant issues with right groin pain that are affecting his daily life. He is undergone 2 right groin injections. The injections. He was scheduled for another groin injection next week.

He did recently have prostate surgery for enlarged prostate. He is having some burning with urination.

**Review of Systems**
**Constitutional:** Denies fever
**Skin:** Denies rash
**Eye:** Denies eye pain
**ENMT:** Denies sore throat and nasal congestion
**Respiratory:** Denies shortness of breath and cough
**Gastrointestinal:** Endorses right groin pain
**Cardiovascular:** Denies chest pain and syncope
**Genitourinary:** Endorses burning with urination
**Musculoskeletal:** Denies back pain and extremity pain
**Neurologic:** Denies headaches, confusion, and weakness
**Psychiatric:** Denies suicidal thoughts and substance abuse
**Allergy/immunologic:** Denies impaired immunity

**Physical Exam**

Vitals & Measurements
**BP:** 128/72
**HT:** 172.72 cm
**General:** no acute distress.
**Skin:** warm, dry.
**Head:** normocephalic, atraumatic.
**Neck:** supple.
**Eyes:** pupils are equal, round, and reactive, vision grossly normal.
**Cardiovascular:** normal peripheral perfusion, no edema
**Respiratory:** respirations are non-labored.
**Chest wall:** no deformity.
**Back:** normal range of motion
**Musculoskeletal:** normal ROM, no swelling, no deformity
**Neurologic:** alert and oriented, grossly non-focal neurologic exam, normal speech observed.
**Psychiatric:** cooperative, appropriate mood and affect.

**Procedure/Surgical History**
- Repair of right inguinal hernia (2017)
- IH (inguinal hernia) (08/05/2015)
- Appendectomy;
- Arthroscopy
- Foot laceration

**Medications**
Medications Administered in Office
No active medications

Home Medications / Unchanged:
**diclofenac topical (diclofenac 1% topical gel)** , 2 gm, Topical, FOUR TIMES DAILY ,
**DULoxetine (DULoxetine 60 mg oral delayed release capsule)** , 60 mg = 1 CAP, Oral, DAILY ,,# 30CAP
**gabapentin (gabapentin)** , 300 mg, Oral, As Needed For Pain,
**hydrOXYzine (hydrOXYzine hydrochloride 25 mg oral tablet)** , 25 mg = 1 TAB, Oral, DAILY As Needed For as needed for anxiety, Take 1-2 TAB as needed before procedure or appointment,# 10TAB
**sulfamethoxazole-trimethoprim (Bactrim DS 800 mg-160 mg oral tablet)** , 1 TAB, Oral, TWICE DAILY , for 7 Days,
**tamsulosin (Flomax 0.4 mg oral capsule)** , 0.4 mg = 1 CAP, Oral, DAILY ,,# 30CAP

**Allergies**
NKA
No Known Medication Allergies

**Social History**
Abuse/Neglect
Feels unsafe at home: No. Safe place to go: Yes. Injuries/Abuse/Neglect in household: No., 07/29/2021
Alcohol
Use: Denies., 09/30/2022
Electronic Cigarette/Vaping
Never, 09/30/2022
Employment/School
Status: Employed. Work/School description: Caretaker/maintenance for Isle au haut homes., 05/20/2020
Home/Environment
Lives with Spouse. Spouse Name: Gail Stinson. Marital Status of Parents: Married. Living situation: Home/Independent., 07/29/2021
Nutrition/Health
Diet: Regular., 07/29/2021
Substance Use History

# EXHIBIT 5

Northern Light.
Maine Coast Hospital

50 Union St. Ellsworth, ME 04605

(207) 664-5311 - Maine Coast Hospital

Patient Name: STINSON, AARON A
DOB: 01/27/1971
Gender: Male
MRN: 1261850
FIN: 381171941

| | |
|---|---|
| Document Type: | Operative Note |
| Service Date: | May 10, 2023 13:00 EDT |
| Result status: | Auth (Verified) |
| Template Title: | Op Note: Right groin exploration, mesh explant, right orchiectomy |
| Performed by: | JACOBUS MD, DYLAN P on May 10, 2023 13:14 EDT |
| Verified by: | JACOBUS MD, DYLAN P on May 10, 2023 13:14 EDT |
| Encounter Info: | 381171941, NL MAINE COAST HOSPITAL, Outpatient Surgery, 05/10/2023 - |

# * Final Report *

**Indication for Surgery**
Mr. Stinson is a 52-year-old gentleman with a history of right inguinal hernia. He has undergone 2 groin surgeries for this hernia. His initial surgery was around 2015. He then had exploration and 2017. Since that time he has continued to endorse chronic right groin pain that is significant in nature and is life style limiting. It was stopping him from doing a significant number of his daily activities and his job. He has tried medical management of the pain as well as groin injections. He is not able to tolerate the side effects from the medications such as Lyrica or gabapentin. He did get some relief from the nerve injections but they were not long-lasting. I counseled him extensively preoperatively regarding a 3rd groin exploration. I did let him know that I could not guarantee that the exploration would resolve his groin pain. He expressed understanding and wished to proceed. Consent was obtained.

**Preoperative Diagnosis**
Right groin pain
History of open right inguinal hernia repair

**Postoperative Diagnosis**
Same

**Procedure**
1. Right groin exploration
2. Explant of mesh
3. Right orchiectomy

**Date of Procedure**
5/10/2023

**Surgeon Primary(s)**
JACOBUS MD, DYLAN P (Primary Surgeon/Provider)

**Assistant**
EDWARDS PAC, JASMINE R (1st Assistant)

**Anesthesia Type**

General
FRALEY MD, LARRY M (Supervisor of Record)
COLON-RIVERA CRNA, CYNTHIA (CRNA)

**Estimated Blood Loss**
20 mL

**Findings**
There was significant scar tissue within the subcutaneous tissues. There were visible Prolene sutures within the external oblique aponeurosis. The mesh appeared to have bunched and curled around the spermatic cord.

**Implant(s)**
None

**Specimen(s)**
1. Right groin tissue
2. Right groin mesh

**Complications**
None

**Description of Surgery**
The patient was identified in the preoperative holding area. He would the correct patient, procedure, site, and side were identified. The operative site was marked. He was transported to the operating room placed supine on the operating room table. Following this general anesthesia using LMA was induced without complication. SCDs were used for DVT prophylaxis. He received the appropriate dose of antibiotics for surgical site infection prophylaxis. His arms were positioned outright making sure to pad all bony prominences. The lower abdomen was prepped and draped in usual sterile fashion. The right groin was examined. He had a previous oblique incision overlying the right groin. Prior to incision another time-out was performed which verified the correct patient, procedure, site, and side. Previous incision was incised using a scalpel. Sharp dissection was carried down through the skin subcutaneous tissues. There was extensive scarring from the subcutaneous tissues to the aponeurosis of the external oblique. Sharp dissection was carried through Scarpa's fascia. The subcutaneous tissues beneath this were scarred extensively. Eventually I was able to identify the aponeurosis of the external oblique by raising a subcutaneous flap and identifying it in a more cephalad manner. I followed the normal plane of tissue inferiorly. I was able to identify what appeared to be Prolene sutures. These appeared to be within the aponeurosis of the external oblique. I dissected out laterally to identify an area of the external oblique aponeurosis that had not been found operated on before. This was incised sharply. I attempted to bluntly dissect beneath the external oblique aponeurosis using Metzenbaum scissors. I was able to open this medially for approximately 2 cm. Digital palpation of the area revealed that there was what appeared to be a bundle of mesh within the medial aspect of the external oblique aponeurosis. At this point I divided the external oblique aponeurosis on the cephalad aspect of the mesh. Thus freeing the mesh from the internal oblique and conjoined tendon. I continued my dissection medially to the pubic tubercle and I was able to free the entire cephalad aspect of the mesh. All Prolene sutures were removed. At this point there did appeared to be some scar tissue versus residual ilioinguinal nerve. I did suture ligate this and sent off the tissue for identification and labeled as right groin tissue. I was not certain that this was the ilioinguinal nerve given the immense amount of scar tissue. . At this point the mesh remained attached to the inferior aspect of the external oblique aponeurosis. I then identified the spermatic cord distal to the external ring. I dissected this proximal and this was intimately involved with the mesh. I attempted to dissect this from a lateral to medial fashion as well. The mesh appeared to have wrapped itself around the cord. Not just that the recreation of the internal ring but along the length of the spermatic cord. This point it became evident that the mesh would not be able to be explanted without transection of the spermatic cord and orchiectomy. I then divided the mesh from the inferior aspect of the external oblique aponeurosis. I was able dissect down to the inguinal ligament. There did not appear to be any Prolene sutures within the Cooper's ligament or Poupart's ligament. The Prolene sutures were divided from the pubic tubercle. The mesh was excised from the spermatic cord. This was sent off for gross pathology. This point the vas deferens and the testicular artery had been divided. These were suture ligated. The right testicle was then delivered from the right hemiscrotum and the attachments were lysed bluntly. The testicle was excised and handed off for pathology. The internal ring was examined. It did not appear significantly enlarged. There is no recurrent hernia through the direct space for the indirect space. The floor of the inguinal canal was reapproximated using 0 Vicryl suture. The wound was thoroughly irrigated. There was no bleeding. The external oblique aponeurosis was then reapproximated using a running 2-0 Vicryl suture. The wound was again thoroughly irrigated. Scarpa's fascia was closed using a 3-0 interrupted Vicryl suture. The subcutaneous tissues were irrigated. The skin was then closed in 2 layers using interrupted 3-0 Vicryl suture in a deep dermal fashion followed by 4-0 Monocryl in a running subcuticular fashion. The skin was cleansed and dried. Dermabond was applied for sterile dressing. The patient was awakened from anesthesia and transported to postanesthesia care unit stable condition. At the end of the operation all sponge, needle, and instrument counts were correct x2.

Patient Name: STINSON, AARON A
MRN: 1261850 FIN: 381171941

**Signature Line**

Electronically Signed By: JACOBUS MD, DYLAN P
Date/Time Signed: 05/10/2023 01:14 PM

# EXHIBIT 6

BRYAN, Jacob DOB: 01/25/1985 (37 yo M) Acc No. 8X502491843 DOS: 01/11/2023

HCA Florida Gainesville Surgical Group

**Bryan, Jacob**
37 Y old Male, DOB: 01/25/1985
Account Number: 8X502491843
1922 NW 27TH ST, GAINESVILLE, FL-32605-3863
Home: 352-665-0335
Guarantor: Bryan, Jacob
Appointment Facility: 456911SGG SURGICAL GROUP GAINESVILLE

**01/11/2023** **PROGRESS NOTE: JEFFREY L ROSE, MD**

## Reason for Appointment
1. F/U - Surgery back in 2017, JR stated may need a nerve ligation

## History of Present Illness
First Point of Contact Screening:
Do any of the following apply to you?
New rash or open sores *No*
Fever and/or chills in the past 7 days *No*
Cough *No*
Muscle or body aches (other than from an injury) *No*
Sore throat *No*
In the past 3 weeks, have you or a close contact traveled outside the United States and you are now ill? *No*

Patient History:
He returns to discuss his chronic groin pain. He has pain in his left inguinal canal radiating toward his left testicle. It is worse with activity. He is ok at night and when resting. Throughout the day, his pain worsens. It is worse with walking, bending, and exercising. He had an open LIH in the distant past. I saw him in 2017 and performed a partial mesh removal and a recurrent hernia repair robotically. He does not have a bulge or sign of a recurrence.

## Current Medications
None

## Past Medical History
High blood pressure.

## Surgical History
Mesh removal

## Family History
Mother: alive
Father: alive

## Social History
Alcohol Use
Patient *does not use alcohol*
Tobacco Status
Patient is *a never smoker*
Marital Status: Single.
Children: no.
Education/School: 12th grade.

## Allergies
N.K.A.

BRYAN, Jacob DOB: 01/25/1985 (37 yo M) Acc No. 8X502491843 DOS: 01/11/2023

## Hospitalization/Major Diagnostic Procedure
No Hospitalization History.

## Review of Systems
GENERAL SURGERY:

Constitutional Negative for fevers, malaise, fatigue, recent weight loss. Eyes Negative for redness, discharge, visual loss/blurred, itching, diplopia, eye pain. Ears, Nose, Mouth, Throat Negative for ear drainage, ear ringing, earache, mouth pain, nose bleeding, sinus problems, sore throat, throat pain, throat swelling, tongue pain, tongue swelling. Cardiovascular Negative for chest pain, palpitations, dyspnea on exertion. Respiratory Negative for wheezing, productive cough. Gastrointestinal Negative for nausea or vomiting, diarrhea, rectal bleeding/blood in stool, jaundice, vomiting blood. Musculoskeletal Negative for extremity pain, extremity swelling, joint pain, joint swelling, neck pain, thoracic pain. Neurological Negative for syncope, confusion, dizziness, focal weakness, gait problems, lightheaded, numbness, seizure, slurred speech, spinning sensation. Psychiatric Negative for confusion, antered mental status. Endocrine Negative for cold intolerance, heat intolerance, polydipsia, polyphagia, polyuria, weight gain, or weight loss. Hematologic/Lymphatic Negative for adenopathy, bleeding, bruising, or petechiae.

## Vital Signs
Ht: 71 in, Ht-cm: 180.34 cm, Wt: 276.8 lbs, Wt-kg: 125.56 kg, BMI: 38.60, Body Surface Area: 2.51, BP: 135/86, Temp: 98.0 F, HR: 75.

## Examination
GENERAL SURGERY:

Constitutional: No acute distress.
Neck: Normal ROM, no JVD.
Eyes: EOMI, no scleral icterus.
Respiratory: no respiratory distress, symmetrical chest rise.
Cardiovascular: normal capillary refill, regular rate.
Gastrointestinal (Abdomen): abdomen soft, non-tender, non-distended, no gaurding, no peritoneal signs. His pain is localized to the left groin and radiates toward his scrotum. There are no bulges or signs of an infection.
Musculoskeletal: Normal ROM, grossly normal appearance.
Extremities: no edema, distal pulses palpable and symmetric.
Skin: skin intact, normal temperature.
Neurologic: A&Ox3, normal speech.
Psychiatric: normal affect, mood, insight/judgment.

## Assessments
1. Left lower quadrant pain - R10.32 (Primary)
2. Other chronic pain - G89.29

## Treatment
### 1. Left lower quadrant pain
Notes: He presents with ongoing left groin pain. I recommended a left groin ultrasound to see if there is a recurrence or epididymitis or other explanation. I encouraged him to remain active. We will follow-up on the results. He is considering a left groin exploration to ligate his left ilioinguinal nerve.

### 2. Others
Notes: High Blood Pressure: Care Instructions, Body Mass Index: Care Instructions material was printed.

## Preventive Medicine
Quality Measures:

Pneumococcal Vaccination - Patients 66 or older:

BRYAN, Jacob DOB: 01/25/1985 (37 yo M) Acc No. 8X502491843 DOS: 01/11/2023

Patient's *Patient refuses*
Influenza Immunization
Patient's *Patient refuses*
Colorectal Cancer Screening:
Patient's *Colorectal cancer screening results were not documented and reviewed, reason not otherwise specified*
High Blood Pressure screening and follow up:
Intervention Order *Yes*
Follow Up for BP reading with PCP/Alternative Provider *Follow-up 2 weeks (finding)*
Lifestyle Recommendation *Lifestyle education regarding hypertension (procedure)*
Weight Assessment
Above Normal BMI Follow-Up *Lifestyle education regarding diet*

## Follow Up

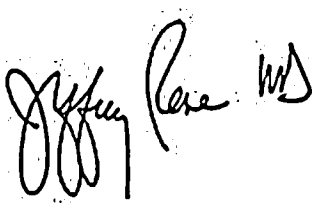
after ultrasound report

## Care Plan Details

Patient Education Notes

**High Blood Pressure: Care Instructions, Body Mass Index: Care Instructions 01/11/2023 05:04:41 PM**

**High Blood Pressure: Care Instructions, Body Mass Index: Care Instructions material was printed 01/11/2023 05:04:43 PM**



**Electronically signed by JEFFREY ROSE , MD, ME42922 on 01/12/2023 at 06:31 PM EST**

**Sign off status: Completed**

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**456911SGG SURGICAL GROUP GAINESVILLE**
**1143 NW 64TH TER**
**GAINESVILLE, FL 326054218**
**Tel: 352-331-1201**
**Fax: 352-331-5273**

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**Progress Note: JEFFREY L ROSE, MD 01/11/2023**

*Note generated by eClinicalWorks EMR/PM Software (www.eClinicalWorks.com)*

# EXHIBIT 7

M·U·S·I·C
Mammography & UltraSound
Imaging Center, PLLC

John M. Elliott, M.D.
Judy M. Yancey, M.D.

Patient: JACOB BRYAN
Patient #: 37275
Referring Physician: JEFFREY ROSE

DOB: 01/25/1985
DOE: 01/30/23
Fax : (352) 331-5273

US EXTREMITY LOWER NON-VASCULAR

**EXAM: Ultrasound of the left groin.**

HISTORY:
Chronic groin pain in left inguinal canal radiating toward left testicle.

FINDINGS: Ultrasound of the left groin was done and no hernia or other abnormality was found.

**IMPRESSION:**

Negative exam.

Electronically approved by: JOHN ELLIOTT MD Date: 01/30/23 09:32


7550 W University Avenue, Suite A | Gainesville, FL 32607 | Tel: (352) 727-4911 Fax: (352) 505-5211
www.mammographyandultrasoundimagingcenter.com

# EXHIBIT 8

BRYAN, Jacob DOB: 01/25/1985 (38 yo M) Acc No. 8X502491843 DOS: 02/08/2023

HCA Florida Gainesville Surgical Group

Bryan, Jacob
38 Y old Male, DOB: 01/25/1985
Account Number: 8X502491843
1922 NW 27TH ST, GAINESVILLE, FL-32605-3863
Home: 352-665-0335
Guarantor: Bryan, Jacob Insurance: Self Pay
Appointment Facility: 456911SGG SURGICAL GROUP GAINESVILLE

02/08/2023 PROGRESS NOTE: JEFFREY L ROSE, MD

## Reason for Appointment
1. Discuss ultra sound results

## History of Present Illness
First Point of Contact Screening:
Do any of the following apply to you?
New rash or open sores *No*
Fever and/or chills in the past 7 days *No*
Cough *No*
Muscle or body aches (other than from an injury) *No*
Sore throat *No*
In the past 3 weeks, have you or a close contact traveled outside the United States and you are now ill? *No*

Patient History:
He returns with the same left groin pain. It begins at his groin crease and radiates toward his testicle. It is worse with activity. He improves with rest. He had a recent ultrasound, but there was no obvious source for his symptoms. I believe he has chronic groin pain from his orginal open inguinal hernia repair that was done elsewhere.
He feels fine otherwise. He is active. He has no other symptoms.

## Current Medications
None

## Past Medical History
High blood pressure.

## Surgical History
Mesh removal

## Family History
Mother: alive
Father: alive

## Social History
Alcohol Use
Patient *does not use alcohol*
Tobacco Status
Patient is *a never smoker*
Marital Status: Single.
Children: no.
Education/School: 12th grade.

## Allergies
N.K.A.

BRYAN, Jacob DOB: 01/25/1985 (38 yo M) Acc No. 8X502491843 DOS: 02/08/2023

## Hospitalization/Major Diagnostic Procedure
No Hospitalization History.

## Review of Systems
GENERAL SURGERY:

Constitutional Negative for fevers, malaise, fatigue, recent weight loss. Eyes Negative for redness, discharge, visual loss/blurred, itching, diplopia, eye pain. Ears, Nose, Mouth, Throat Negative for ear drainage, ear ringing, earache, mouth pain, nose bleeding, sinus problems, sore throat, throat pain, throat swelling, tongue pain, tongue swelling. Cardiovascular Negative for chest pain, palpitations, dyspnea on exertion. Respiratory Negative for wheezing, productive cough. Gastrointestinal Negative for nausea or vomiting, diarrhea, rectal bleeding/blood in stool, jaundice, vomiting blood. Musculoskeletal Negative for extremity pain, extremity swelling, joint pain, joint swelling, neck pain, thoracic pain. Neurological Negative for syncope, confusion, dizziness, focal weakness, gait problems, lightheaded, numbness, seizure, slurred speech, spinning sensation. Psychiatric Negative for confusion, antered mental status. Endocrine Negative for cold intolerance, heat intolerance, polydipsia, polyphagia, polyuria, weight gain, or weight loss. Hematologic/Lymphatic Negative for adenopathy, bleeding, bruising, or petechiae.

## Vital Signs
Ht: 71 in, Ht-cm: 180.34 cm, Wt: 274.6 lbs, Wt-kg: 124.56 kg, BMI: 38.29, Weight Change: -2.2 lb, Body Surface Area: 2.50, BP: 130/82, Temp: 98.0 F, HR: 75.

## Examination
GENERAL SURGERY:

Constitutional: No acute distress.
Neck: Normal ROM, no JVD.
Eyes: EOMI, no scleral icterus.
Respiratory: no respiratory distress, symmetrical chest rise.
Cardiovascular: normal capillary refill, regular rate.
Gastrointestinal (Abdomen): abdomen soft, non-tender, non-distended, no gaurding, no peritoneal signs. He has well healed surgical scars. There is no palpable lump in his left side.
Musculoskeletal: Normal ROM, grossly normal appearance.
Extremities: no edema, distal pulses palpable and symmetric.
Skin: skin intact, normal temperature.
Neurologic: A&Ox3, normal speech.
Psychiatric: normal affect, mood, insight/judgment.

## Assessments
1. Left lower quadrant pain - R10.32 (Primary)

## Treatment
**1. Left lower quadrant pain**
Notes: I discussed his options with him: referral to pain management, PT, or a groin exploration and nerve ligation. He did not improve with a posterior hernia repair. He is anxious to have the nerve ligated to have some relief. We plan a Left Groin Exploration with an Ilioinguinal Nerve Ligation. I explained the risks and benefits. We will try to schedule it for the next 2-3 weeks at his convenience.

**2. Others**
Notes: Body Mass Index: Care Instructions, High Blood Pressure: Care Instructions material was printed.

## Preventive Medicine
Quality Measures:
Pneumococcal Vaccination - Patients 66 or older:
Patient's *Patient refuses*

BRYAN, Jacob DOB: 01/25/1985 (38 yo M) Acc No. 8X502491843 DOS: 02/08/2023

Influenza Immunization
Patient's *Patient refuses*
Colorectal Cancer Screening:
Patient's *Colorectal cancer screening results were not documented and reviewed, reason not otherwise specified*
High Blood Pressure screening and follow up:
Intervention Order *Yes*
Follow Up for BP reading with PCP/Alternative Provider *Follow-up 2 weeks (finding)*
Lifestyle Recommendation *Lifestyle education regarding hypertension (procedure)*
Weight Assessment
Above Normal BMI Follow-Up *Lifestyle education regarding diet*

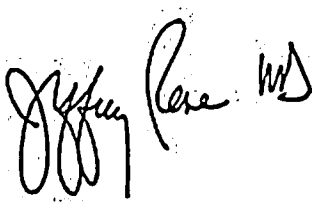
## Follow Up

return for surgery

## Care Plan Details

Patient Education Notes

**Body Mass Index: Care Instructions, High Blood Pressure: Care Instructions 02/08/2023 09:35:26 AM**
**Body Mass Index: Care Instructions, High Blood Pressure: Care Instructions material was printed 02/08/2023 09:35:28 AM**



**Electronically signed by JEFFREY ROSE , MD, ME42922 on 02/14/2023 at 03:43 PM EST**

**Sign off status: Completed**

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**Fax: 352-331-5273**

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**Progress Note: JEFFREY L ROSE, MD 02/08/2023**

*Note generated by eClinicalWorks EMR/PM Software (www.eClinicalWorks.com)*