

Fistula Repair Module Contents & Description List

Direct Relief's **Fistula Repair Module** is a standardized pack of high-quality medicines and surgical supplies necessary for fistula repair surgery, available at no cost to qualified health facilities providing fistula care services worldwide. The contents of the Fistula Repair Module have been determined based on recent surveys of clinical experience and best practices, and consultations with expert providers in the field.

The quantity of items per **Fistula Repair Module** is calculated in units of 50 surgical cases, and can be provided in multiples based on the case load of the facility. Detailed information about the products selected and recommended usage is provided in the Fistula Repair Module Content Description List.

Material Description	Unit	Qty/50 Cases
Part A: Standard Materials		
The materials in this section are included in every Fistula Repair Module		
Antibiotics		
Ceftriaxone_1g/15ml_10 single dose vials	Pack	12
Ciprofloxacin Hydrochloride_500mg_100 Tablets	Bottle	1
Metronidazole_250mg_100 Tablets	Bottle	2
Metronidazole_500mg/100ml_24 IV bags	Pack	6
Analgesics		
Ibuprofen_200mg_1000 Tablets	Bottle	1
Diclofenac Sodium_50mg_100 Tablets	Bottle	2
Acetaminophen_500mg_1000 Tablets	Bottle	1
Additional Medications		
Bisacodyl_5mg_100 Tablets	Bottle	1
Oxybutinin Chloride extended release_Ditropan XL_5mg_84 Tablets	Bottle	15
Surgical Supplies		
Exam Gloves_Medium_200 per pack	Pack	4
Exam Gloves_Large_200 per pack	Pack	4
Surgical Blades_#15_100 per pack	Pack	1
Surgical Blades_#11_100 per pack	Pack	1
Needle_21G x 1" _100 per pack	Pack	4
Needle_23G x 1" _100 per pack	Pack	4
Syringe_Catheter Tip_60mL_40 per pack	Pack	8
Foley Catheter_16Fr_5cc Balloon_Silicon Coated_12 per pack	Pack	4
Foley Catheter_18Fr_5cc Balloon_Silicon Coated_12 per pack	Pack	2
Foley Catheter_24Fr_5cc Balloon_Silicon Coated_12 per pack	Pack	1
Foley Catheter_12Fr_5cc Balloon_Silicon Coated_12 per pack	Pack	1
Urinary Drainage Bag, 2000mL, with Mono-Flo, Sterile_20 per case	Case	3
Ureteral Catheter_5Fr_Straight Tip_69cm_10 per case	Case	2
Ureteral Catheter_6Fr_Straight Tip_69cm_10 per case	Case	2
Nursing Supplies		
Syringe, 3ml, Safety-Lok, Luer-Lok tip, Sterile_100 per pack	Pack	4
Syringe, 5ml, Safety-Lok, Luer-Lok tip, Sterile_50 per pack	Pack	6

Syringe, 10ml, Safety-Lok, Luer-Lok tip, Sterile_100 per pack	Pack	4
Syringe, 20ml, Luer-Lok tip, Sterile_40 per pack	Pack	2
IV Catheter_18G x 1-1/4", Sterile_50 per pack	Pack	2
IV Catheter_20G x 1" _50 per pack	Pack	1
IV solution set_continuous flow_112" _48 per case	Case	1
Surgical tape_hypoallergenic cloth tape_2.5cm x 9.1 m_12 rolls per pack	Pack	2
Surgical tape_hypoallergenic cloth tape_5.1 cm x 9.1 m_6 rolls per pack	Pack	2
Female Straight Catheter, 14Fr, 7.2 inches_50 per pack	Pack	6
Pad_Abdominal_Dermacea_8"x10" _18 pads per pack	Pack	4
Gauze Sponge_12-Ply_4"x4" _STRLE_100 sponges per pack	Pack	20
Gauze Roll_8-Ply_4.5"x3yd_100% Cotton_STRLE_100 rolls per case	Case	1
Underpad for bed_23 x 24 inches_200 per case	Case	3
Maternity Pad_Post Childbirth_4x12" _168 pads per case	Case	2
Part B: Custom Materials		
The materials in this section are customizable based on health facility needs		
Surgical Gloves		
8 packs provided per 50 cases, size dependent on surgical team needs		8
Surgical Gloves_Size 7_Latex_STRLE_40 per pack	Pack	
Surgical Gloves_Size 7.5_Latex_STRL_40 per pack	Pack	
Surgical Gloves_Size 8_Latex_STRLE_40 per pack	Pack	
Anesthesia Supplies		
5 packs provided per 50 cases, needle size dependent on anesthesiologist needs		5
Spinal Needle_22G x 3.5" _Whitacre needle_10 per pack	Pack	
Spinal Needle_25G x 3.5" _Whitacre needle_10 per pack	Pack	
Introducer_Needle_Spinal_20G x1.25" _25 per pack	Pack	
Spinal Needle_25G x 3" _Quincke needle_25 per pack	Pack	
Suture		
Bladder closure		4 boxes
Vicryl, Size 3-0, CT-2 26mm, 1/2 circle taper point, undyed braided, 70cm_J232H	36/Pack	
Vicryl, Size 2-0, UR-6 26mm, 5/8 circle taper point, violet braided, 70cm_J602H	36/Pack	
Vaginal closure		3 boxes
Vicryl, Size 2-0, CT-2 26mm, 1/2 circle taper point, violet braided, 70cm_J333H	36/Pack	
Vicryl, Size 2-0, CT-2 26mm, 1/2 circle taper point, undyed braided, 70cm_J269H	36/Pack	
Vicryl, Size 2-0, UR-6 26mm, 5/8 circle taper point, violet braided, 70cm_J602H	36/Pack	
Fascial closure		1 box
Prolene, Size 0, CT-1, 36mm, 1/2 circle taper, blue monofilament, 75cm_8424H	36/Pack	
Vicryl, Size 0, CT-2, 26mm 1/2 circle taper point, undyed braided, 70cm_J270H	36/Pack	
Urethral reconstruction and ureteral reimplantation		1 box
Vicryl, Size 4-0, RB-1 17mm,1/2 circle taper, undyed braided, 70cm_J214H	36/Pack	
Vicryl, Size 5-0, RB-1 17mm, 1/2circle taper, undyed braided, 70cm_J213H	36/Pack	

Skin closure		1 box
Vicryl, Size 3-0, PS-2 19mm, 3/8 circle reverse cutting, undyed braided, 70cm_J427H	36/Pack	
Bowel closure		2 boxes
Vicryl, Size 3-0, SH 26mm 1/2 circle, violet braided, 70cm_J316H	12/Pack	
Abdominal Ties		1 box
Silk Ties, Size 3-0, Permahand suture with dispensing reel, 366cm, black braided_ LA54G	12/pack	

***Suture requests are customizable per the needs of the fistula center and determined at the time of order placement.**

For questions about the contents of the module or about partnership with Direct Relief, please contact **Jessica Koval**:
JKoval@directrelief.org.

To apply for a Fistula Repair Module, please visit:
www.directrelief.org/fistulaapplication

Fistula Repair Module Content Description List

Overview

Direct Relief's **Fistula Repair Module** is a standardized pack of high quality medicines and surgical supplies necessary for fistula repair surgery that is provided at no cost to qualified health facilities providing fistula care services worldwide. Direct Relief has engaged leading healthcare companies to donate many of the items included in the **Fistula Repair Module**, and additional essential medicines and supplies have been purchased directly to deliver a more comprehensive package of materials. While the **Fistula Repair Module** does not include everything that a hospital providing fistula care would require, it does provide an essential set of critically needed consumable supplies.

Expert Consultation

The contents of the **Fistula Repair Module** have been determined based on extensive consultations with providers in the field. The antibiotics section has been developed in consultation with an Infectious Disease Specialist with experience in the developing world who sits on Direct Relief's Medical Advisory Committee. Direct Relief realizes that the practice of fistula repair involves many individual choices and preferences, and they have done their best to standardize module contents and offer options where appropriate (e.g., in the area of suture and anesthesia supplies).

This Content Description List provides detailed information about the product selections included in the **Fistula Repair Module**. Many of the contents in the Module are standard and do not require explanation. This content description list is limited to the items that benefit from additional clarification in order to describe the rationale for including such items, and to recommend appropriate clinical use of the products based on expert consultation.

Antibiotics

Use of antibiotics is a particularly difficult area to standardize; this advice does not substitute a clinician's personal expertise and specific antibiotic resistance data in the geographic area they practice, if this information is available. However, evidence is emerging that antibiotic resistance among common pathogens encountered during vesicovaginal fistula (VVF) care is a substantial problem. In many places that have been investigated (e.g. Liberia, Benin, Nigeria, and Ethiopia), many of the common gram-negative uropathogens are resistant to the antibiotics traditionally used, such as ampicillin and trimethoprim/ sulfamethoxazole. In some areas, common pathogens like the Klebsiella family have acquired multi-drug resistance to the point where there are almost no remaining useful antibiotic choices.

Given that prophylaxis in settings of multi-drug resistant uropathogens leave few rational options for antibiotic choice, Direct Relief's specialist suggests the routine use of a single dose IV ceftriaxone preoperatively. For cases of rectovaginal fistula (RVF), both ceftriaxone and IV metronidazole should be used, once again as a single pre-operative dose.

For patients with post-operative fever that is felt to be bacterial in origin, Direct Relief's specialist suggests a combination of ciprofloxacin and metronidazole. Metronidazole can be given either orally or intravenously, depending on the severity of the illness. If infection with a multi-resistant organism is suspected, intravenous Imipenem (cilastatin sodium-imipenem) is recommended. Imipenem is known to have risk of seizures and does

require dose adjustment in the setting of renal insufficiency, but can be a lifesaving medication in the setting of severe illness from multidrug resistant uropathogens. Providers should limit their use of precious supply of imipenem to cases of life-threatening infection.

Analgesics

In the area of analgesic medications, please realize that Direct Relief is often unable to ship controlled substances like narcotics to the countries where fistula repair surgeries are performed. Therefore, the medications available from Direct Relief are limited to non-narcotic agents, namely diclofenac, ibuprofen, and acetaminophen.

Additional Medications

Oxybutinin Chloride, Ditropan XL: Direct Relief is excited to add the option of Ditropan XL for treatment of urinary frequency, urgency, and urge incontinence. This is the first time that one of the “newer” medications for this clinical setting has become available. Ditropan XL is oxybutynin in an extended release form, such that it is given only once per day at 5mg, 10mg, or 15mg.

Surgical Supplies

Surgical Blades: Different surgeons prefer different types of scalpel blades. While a few use #11 or #12 blades, the most commonly employed types are #15 for vaginal incisions and #10 blades for abdominal incisions. The **Fistula Repair Module** includes both size #15 and #10 blades.

Foley Catheters: Urinary catheters are another area of strong feelings ranging across a wide variety of products. In urology, 16F or 18F catheters are considered to be the “normal” size for an adult. A number of fistula surgeons have independently noted that the 100% silicone catheters are quite stiff and worrisome for potential damage to a new repair, and that the balloons on silicone catheters seem more prone to spontaneous rupture. Therefore, the catheters in the **Fistula Repair Module** are latex with a silicone coating. Urethral surgery often requires a smaller catheter (12F is provided), and for women with hematuria with clot after repair, a large-bore catheter is needed to flush clots from the bladder (24F is provided).

Ureteric catheters for marking the location of the ureters during dissection are included in size 5F and 6Fr, the two most commonly used sizes.

Female Straight catheters are used for testing for and managing urinary retention after surgery. Evidence is rapidly building that significant numbers of women who appear to be doing well after the removal of their Foley catheter actually suffer from poor bladder emptying or even urinary retention. Providers should develop a protocol for checking the post-void residual volume of each patient at least once after the catheter is removed. For those patients found to be retaining urine, ample supply of straight catheters is provided for intermittent catheterization.

Anesthesia Supplies

In the area of spinal anesthesia, an anesthetist with experience in fistula anesthesia was consulted to help identify the most commonly used needles and agents for spinal anesthesia. Options of 22G or 25G Whitacre with introducer needle or 25G Quincke needle are available for selection, depending on anesthetist preference.

Drugs for general anesthesia with the appropriate strength have been difficult to source from suppliers in the U.S. and are therefore not available in the module at this time.

Suture

Perhaps no single area is more debated than the choice of suture material for fistula surgery. Because suture and needles come in a huge variety of combinations, it is difficult to have complete consensus among fistula surgeons.

As part of the **Fistula Repair Module**, Direct Relief has attempted to think in terms the basic steps involved for fistula repair and provide at least two choices of suture that could be used for each. The surgeon at your facility may specify his or her preference when ordering from Direct Relief. If your particular preference is not available, other choices would be considered, but only if you can provide compelling evidence of why your particular choice must be provided.

Bladder closure: Bladder closure requires absorbable suture. Though there are a wide variety of practices, urologists tend to close bladder tissue with 3-0 absorbable suture. Use of the smallest suture that is effective in a particular situation would fall beneath what the FIGO Fistula Surgeon Curriculum would call “respect for tissues.” Vicryl size 2-0 is included as an option if this is your preference, although if you were trained to use heavier suture in bladder closure, you may want to try using 3-0 instead.

Vaginal closure: Vaginal closure can require use of needles at awkward angles and under significant torque during placement, so a strong needle is best. Based on comparison of requested suture/needle, two options are listed—Vicryl on a CT-2 needle and Vicryl on a UR-6 needle. Some providers feel more confident using a 5/8 curve needle, which is why Vicryl on a UR-6 needle is included as a third choice.

Fascial Closure: Some surgeons prefer non-absorbable suture to close the abdomen (Prolene is offered), while others use absorbable suture in the same setting (0 Vicryl is offered).

Bowel Closure: This is generally accomplished with 3-0 absorbable suture on a fairly fine needle (offered is a 3-0 Vicryl with an SH needle).

Skin Closure: For this category, there is significant variability in preference, and the module contains 3-0 Vicryl which is also suitable for sub-cuticular closures.

Urethral Reconstruction and Ureteral Reimplantation These delicate structures require the use of finer absorbable suture material. Both 4-0 and 5-0 Vicryl and Polysorb sutures on small atraumatic needles are offered.

Abdominal Surgery: Since choices for abdominal, bowel, and skin closure have already been mentioned, the remaining suture for abdominal repairs is 3-0 silk ties to use for vessel ligation.

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