



XtremityTT™ FLEX: Instructions For Use

Introduction:

The XtremityTT™ FLEX is a flexible inner socket (FIS) that provides uniform wall thickness, easy fabrication with minimal lab space and equipment, and reduced material waste relative to traditional flexible inner sockets. The XtremityTT™ FLEX Preforms are specifically designed to be simple and easy to form with excellent melt strength. The XtremityTT™ FLEX is compatible with the XtremityTT™ Socket System as well as traditional laminated sockets.

Intended use:

The XtremityTT™ FLEX is intended to be used in combination with the XtremityTT™ Socket System or traditional prosthetic socket. XtremityTT™ FLEX should only be provided under the direct supervision of a certified prosthetist. The device is for single patient use.

Product Identification:

Brand: XtremityTT™ FLEX

Category: Leg Prosthesis

Indications for Use:

- Transtibial Amputation
- Distal limb circumference between 24-38cm circumference, measured over a liner at 4cm from the distal end
- Proximal limb circumference that falls within the indicated range on the XtremityTT™ FLEX Size Selection Chart (page 2) according to the length measurement from the mid patella tendon (MPT)

Equipment Needed:

- XtremityTT™ Benchtop Heating Unit
- Silicone Lid Cap for Benchtop Heating Unit
- Heat Gun
- Heatproof Gloves
- Talcum Powder

Sizing the XtremityTT™ FLEX:

Using the correct size of XtremityTT™ FLEX is critical for optimal outcomes. The XtremityTT™ FLEX comes in one profile and three sizes. It will accommodate a wide range of limb shapes and sizes. Extremely conical or unusual shaped limbs may fall outside of our sizing indications. The XtremityTT™ FLEX is 3.5mm thick and may thin slightly when forming. Follow the proximal limb circumference guide on page 2 to ensure the FIS maintains its uniform wall thickness without being overstretched.



Size Ranges (identified from circumferential measurement 4cm from distal end)

Size 24: 24 – 27.9 cm

Size 28: 28 – 32.9 cm

Size 33: 33 – 38 cm

Size Selection Instructions for XtremityTT™ FLEX:

***Note:** the total length from your most proximal trim line to the distal end must measure **29cm** or less.

1. **Distal Circumference:** First, take a circumferential measurement 4cm from the distal end of the limb model to determine the FIS size (across the first row of the chart).
2. **Length:** Next, take a length measurement from the Mid-Patella Tendon (MPT) to the distal end of the limb model. Round to the nearest cm.
3. **Proximal Circumference:** Finally, take a circumferential measurement at MPT. Use the length and MPT circumference to ensure that the model does fit within the XtremityTT™ FLEX sizing limits so that it is not over stretched.

Size	Size 24	Size 28	Size 33
1. Distal Circumference →	Distal 24-27.9(cm)	Distal 28-32.9(cm)	Distal 33-38(cm)
2. Limb Length: MPT to Distal End ↓	3. MPT Circumference (cm) →		
7	26.0 – 28.5	28.5 – 30.4	28.0 – 30.0
8	26.2 – 29.0	29.0 – 31.1	28.2 – 31.0
9	26.5 – 29.5	29.5 – 31.8	28.5 – 31.5
10	26.9 – 30.0	30.0 – 32.5	28.7 – 31.5
11	27.2 – 30.0	30.0 – 33.2	29.0 – 32.0
12	27.6 – 30.5	30.5 – 33.8	29.2 – 32.5
13	27.9 – 31.0	31.0 – 34.5	29.5 – 32.5
14	28.2 – 31.5	31.5 – 35.2	29.7 – 33.0
15	28.6 – 32.0	32.0 – 35.9	29.9 – 33.5
16	28.9 – 32.5	32.5 – 36.6	30.2 – 33.5
17	29.2 – 33.0	33.0 – 37.2	30.4 – 34.0
18	29.6 – 33.5	33.5 – 37.9	30.7 – 34.5
19	29.9 – 34.0	34.0 – 38.6	30.9 – 35.0
20	30.3 – 34.5	34.5 – 39.3	31.2 – 35.0
21	30.6 – 35.0	35.0 – 40.0	31.4 – 35.5
22	30.9 – 35.5	35.5 – 40.6	31.7 – 36.0
23	31.3 – 36.0	36.0 – 41.3	31.9 – 36.7
24	31.5 – 36.0	36.0 – 42.0	32.2 – 37.0
25	31.9 – 36.5	36.5 – 42.7	32.4 – 37.3
26	32.3 – 37.0	37.0 – 43.4	32.7 – 37.5
27	32.6 – 37.5	37.5 – 44.1	32.9 – 37.5



****Critical to the success of the XtremityTT™ FLEX****

Preparing the Limb Model:

The FIS will pick up any defects in the model, so make sure the model is smooth. When preparing the positive model for the XtremityTT™ FLEX, plan your global reductions for a 1 ply fit to accommodate for material shrinkage. This equates to approximately 0.75% less global reduction compared to reductions for a 0 ply fit.

When using XtremityTT™ FLEX with XtremityTT™ Socket, refer to XtremityTT Instructions For Use for additional limb model preparation and trim line recommendations.

Note: Do NOT use a nylon when pulling the FIS over the positive model. Remove all excessive build-ups proximal to the trim lines.

Preparing the XtremityTT™ FLEX for Heating:

Place the FIS carefully in the Benchtop Heating Unit on the pedestal so that it is not tilted in any direction. Seal the hole in the center of the Benchtop Heating Unit lid with the silicone lid cap to ensure heat does not escape.

Benchtop Heating Unit Settings:

The Benchtop Heating Unit has a setting for FIS (accessible by pressing the FIS button on the heating unit keypad). The FIS Mode was specially designed to heat the XtremityTT™ FLEX. **The temperature and time settings for the FIS mode may require a one-time adjustment, see instructions below. Be sure to set the Benchtop Heating Unit to FIS mode each time you form an XtremityTT™ FLEX.**

To confirm/adjust temperature and time settings:

1. Power the unit on and press the FIS button to select FIS mode. The temperature setting displayed should be 335°. IF the temperature setting is not 335°:
 - a. Press and hold the “down” arrow until the temperature LED drops in value. When this happens, release the down arrow, and then press the up arrow to reach 335°
 - b. To save this temperature setting, press and hold the Power Button and the display will turn OFF and then back ON. This indicates that the unit is reset and the new temperature is saved. Do not release your finger until the display turns back on
2. Press START to accept the new temperature setting. The display should then read “5:00” to signify the time setting. IF the time setting is not 5:00:
 - a. Press and hold the “down” arrow until the time LED drops in value. When this happens, release the down arrow, and then press the up arrow to reach 5:00



- b. To save this time setting, press and hold the Power Button and the display will turn OFF and then back ON. This indicates that the unit is reset and the new time is saved. Do not release your finger until the display turns back on
3. Press START again to accept this setting and begin heating.

By following the procedure above, any changes to the temperature and time settings will be saved and this procedure will not need to be repeated. Simply press the FIS button to return to these settings. If you plan to heat an XtremityTT™ socket, press the SOCKET button and it should read 350°. Proceed with normal heating instructions of the XtremityTT™ socket, ensuring that the temperature setting is at 350° and time setting is 5:00.

Heating of XtremityTT™ FLEX:

1. Power the heating unit on
2. Press the FIS button (display temperature should read 335°)
3. Press Start to accept the FIS temperature setting
4. Press Start again to accept the time setting (5:00) and begin heating
5. Total heating time is 20-25 minutes

If planning to immediately heat another XtremityTT™ FLEX or XtremityTT™ socket, remove the lid from the heating unit for at least 10 minutes to allow the heating unit to cool before starting again. In the event an error is made in forming, the FIS can be reheated and reformed before it has been trimmed in most cases. Once it has been trimmed, the XtremityTT™ FLEX cannot be fully reheated in the Benchtop Heating Unit and reshaped.

Shaping the XtremityTT™ FLEX:

1. Once heated, remove the XtremityTT™ FLEX from the heating unit with gloves and add talcum powder to the inside of the XtremityTT™ FLEX Preform
2. Gently stretch the proximal opening as it is fitted over the positive model
3. With 4 fingers on both hands inside anterior and posterior brim of the Preform, pull the Preform from the proximal brim with a slight back and forth twisting motion to get an even pull. (Fig. 1)
4. As the XtremityTT™ FLEX approaches distal contact, use opposing hands on the midsection if needed to gently pull it fully onto the model until distal contact is made
5. Check for distal contact by pressing the distal end gently to assure it is fully seated. Do not push from the distal end of the XtremityTT™ FLEX in an attempt to make distal contact with the positive mold, as wrinkles or deformation of the material may occur
6. Pull a latex or similar sealing sleeve over the XtremityTT™ FLEX brim to achieve vacuum seal and apply vacuum. Maintain a vacuum until the FIS reaches room temperature. This should take about 10 minutes**



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**Unlike typical sheet formed Flexible Inner Sockets, the XtremityTT™ FLEX is ready for definitive socket fabrication over the XtremityTT™ FLEX once it reaches room temperature.



Figure 1: Forming an Xtremity™ FLEX

Sizing the XtremityTT Socket:

After the XtremityTT™ FLEX has been formed onto a limb model, take new measurements over the formed XtremityTT™ FLEX on the positive model. Follow the XtremityTT™ socket measuring guidelines to select the correct XtremityTT Socket Preform size from the XtremityTT Socket Sizing Chart.

If the XtremityTT™ Socket Preform size needs to be determined before the XtremityTT™ FLEX is formed, add 2.0 cm to the distal and MPT circumference measurements and add 4 mm to the length measurement from MPT. Use these measurements and the Sizing Chart to select the correct size.

Reminder: the length measurement from the most proximal trim line to the distal end of the positive model cannot exceed 29cm when using XtremityTT™ FLEX.

Forming the XtremityTT™ Socket over the XtremityTT™ FLEX:

- With the XtremityTT™ FLEX formed on the model, apply a vacuum nylon, twisted and reflected, or with a smooth seam
- If planning to use Velcro to attach the XtremityTT™ FLEX to the XtremityTT™ Socket, adhere both sides of velcro to the XtremityTT™ FLEX to create space for them once the XtremityTT™ Socket is formed. For a smooth transition, place the vacuum nylon over the velcro before pulling the XtremityTT™ Socket. Double sided tape can also be used



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in place of velcro to help hold the FIS solid inside the socket. When this is used, "dummy" material is not needed to create space

- Determine the correct XtremityTT™ Socket Preform size using proper measurements and Socket Preform Sizing Chart
- Heat and pull the XtremityTT™ Socket Preform according to XtremityTT™ Socket Instructions For Use. Talcum powder or silicone spray can be used
- Vacuum form the XtremityTT™ Socket and leave on the model for 1 hour to cool. This additional time will prevent shrinkage of the XtremityTT™ FLEX

Finishing the XtremityTT™ FLEX and the XtremityTT™ Socket:

It is critical to place a centered hole in the distal end of the finished XtremityTT™ FLEX to achieve optimal suspension with Pin-Lock, Suction or Vacuum. Hole placement is important to not block air or pin passage. Use the following directions to position the hole.

*Do NOT trim or remove the XtremityTT™ FLEX or XtremityTT™ Socket from the limb model.

For ALL suspension systems, mark the distal end of the XtremityTT™ FLEX with a Sharpie through the hole in the base of the socket. (Fig. 2)



Figure 2: Marking Drilling Location

Follow these instructions for each suspension type.

Pin Lock:

- Use a Sharpie to draw a circle through the hole on the base of the XtremityTT™ Socket
- Use a 3/16" drill bit to drill a guide hole through the center of the marked circle on the XtremityTT™ FLEX until it reaches the limb model
- Trim the XtremityTT™ Socket and XtremityTT™ FLEX. Knock off the XtremityTT™ Socket off the model, leaving the XtremityTT™ FLEX still in place on the positive limb model



- Use a **1-1/4"** hole saw to drill out the hole in the bottom of the XtremityTT™ FLEX while still on the plaster model
- Remove the XtremityTT™ FLEX from the limb model
- Smooth, bevel and buff the hole as desired to allow ease of passage of the plunger pin
- Smooth, buff and finish the proximal brim of both the XtremityTT™ FLEX and the XtremityTT™ Socket
- Apply double sided tape or velcro to prevent movement between the XtremityTT™ FLEX and XtremityTT™ Socket if desired

Suction:

- Use a Sharpie to draw a circle through the hole on the base of the XtremityTT™ Socket
- Use a 3/16" drill bit to drill a guide hole through the center of the marked circle on the XtremityTT™ FLEX until it reaches the limb model
- Remove both the XtremityTT™ FLEX and the XtremityTT™ Socket from the limb model
- Smooth, buff and finish the proximal brim of both the XtremityTT™ FLEX and the XtremityTT™ Socket
- Apply double sided tape or velcro to prevent movement between the XtremityTT™ FLEX and XtremityTT™ Socket if desired

Vacuum:

- Use a Sharpie to draw a circle through the hole on the base of the XtremityTT™ Socket
- Use a 3/16" drill bit to drill a guide hole through the center of the marked circle on the XtremityTT™ FLEX until it reaches the limb model
- Use a 1/16" drill bit to drill a hole from the distal end, through the center of the Base Vacuum Port, through the XtremityTT™ FLEX into the limb model
- Remove both the XtremityTT™ FLEX and the XtremityTT™ Socket from the limb model
- Smooth, buff and finish the proximal brim of both the XtremityTT™ FLEX and the XtremityTT™ Socket
- Apply double sided tape or velcro to prevent movement between the XtremityTT™ FLEX and XtremityTT™ Socket if desired

Adjusting the XtremityTT™ FLEX and XtremityTT™ Socket:

Traditional flexible inner sockets are often used to adjust fit by grinding on the flexible material, adding padding in between it and the socket, or cutting windows into the definitive socket. This practice is no longer needed with the XtremityTT™ Socket system.

To Adjust:

- Remove the XtremityTT™ FLEX from the XtremityTT™ Socket
- Using a heat gun, gently heat the outside and inside of the XtremityTT™ Socket, keeping the heat gun at least 2 inches from the socket, slowly moving it for even heating. Once pliable, adjust the XtremityTT™ Socket as necessary










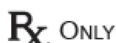
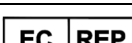




- The XtremityTT™ FLEX will flex to conform to this adjustment; however, the XtremityTT™ FLEX can also be heated and adjusted in the same manner as the Socket. Once both the XtremityTT™ Socket and XtremityTT™ FLEX are warm enough to form, quickly insert the FIS and hand form the materials to the desired shape

Care and Cleaning:

XtremityTT™ FLEX can be cleaned with soap and water, isopropyl alcohol, or any water-based spray cleaner. Solvents such as acetone and Goo-Off can be used to remove tape gum and may change the surface texture but will not harm the material.

Identification of symbols used on product labeling:

Symbol	Meaning or Definition
	Catalogue Number – Reference Number
	Serial number
	Expiration date of product
	Manufacturer
	Consult the instructions for use for important warnings and precautions that are not on the device itself
	Consult instructions for use
	Keep away from sun/heat
	Keep dry
	Do not use if package is damaged
	Prescription use only
	Authorized representative in the European Community
	Product is provided nonsterile
	Do not reuse between patients



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