BIOMET ®
MICROFIXATION

One Surgeon. One Patient. ℠

Custom Temporomandibular Joint (TMJ)
Part Numbers: CP751506
Lot Numbers: 478490

Biomet Danmark APS
HATTINGVEJ 7
HORSENS, DK

Dear Distributor,

This notice is to inform you of an Urgent Medical Device Field Safety Corrective Action initiated by Biomet Microfixation which involves the following device distributed to your facility:

Temporomandibular Joint (TMJ) Patient Matched Left Fossa,
Part #CP751506, Lot #478490

Biomet Microfixation has initiated this notice following an investigation which identified that the device received by your facility is not matched to the appropriate patient and therefore will not fit that patient's anatomy. The potential health hazards associated with this event are a delay in the surgery, post operative posterior dislocation, or a revision surgery.

We shipped this device to your facility on 09/04/2013.

This action requires the immediate location and discontinued use of the item above, and immediate return to Biomet Microfixation. Specifically, you are **REQUIRED** to take the following steps**:**

- Immediately quarantine the device identified above.

- Please return the device utilizing priority mail via, FEDEX Acct# 290613205 or UPS Acct# 6R696V to:

    Biomet Microfixation
    Attn: Rachel Osbeck
    1520 Tradeport Drive
    Jacksonville, FL 32218

- If you have further distributed this item to medical facilities, you MUST notify them of this action by providing a copy of this notice to the person responsible for receiving field safety corrective action notices. However, you are charged with the location and return of this item.

- A replacement device is being manufactured and will be shipped priority upon completion.

Thank you in advance for your assistance and prompt attention to this matter. We apologize for any inconvenience this may cause. Questions related to this notice should be directed to Rachel Osbeck, 904-741-9448 or 904-239-6671.

Sincerely,

Rachel Osbeck
Director, Quality Assurance and Regulatory Affairs