Release Status:Issued and Effective

IRRIGATION SETS (MALTA ACCESS CODES) USER NEEDS AND INTENDED USE

Approvals

Signatures below indicate approval that all content has been transferred from already approved documentation to this one.

FUNCTION	NAME	SIGNATURE	DATE
R&D (Author)	Simon Jordan	(See Electronic Signature)	(See stamp)
Quality	Cynthia Psaila	(See Electronic Signature)	(See stamp)

PARENT DOCUMENT(S):   GQP-09-02
(current rev.)
OWNER CODE: GQC

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BAXTER CONFIDENTIAL - INTERNAL USE ONLY

FORM NO.:   GQT-09-02-01
REVISION: A
ISSUE DATE: 28-DEC-2016
EFFECTIVE DATE: 01-JUL-2017

Issued Date:18-Mar-2021   Effective Date:18-Mar-2021

BAXTER DHF NO: 81548-DHF-ERD	**DOCUMENT NO:** BXU535425
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes) User Needs and Intended Use	**REVISION:** D

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1   PURPOSE

The purpose of this document is to define the User Needs and Intended Uses of Malta design owned Access Codes.

2   SCOPE

The scope of this document is to provide an overview of the User Needs and Intended Use requirements applicable to the product codes in the following DHF families:

- Irrigation Sets

3   UPDATES IN SCOPE

All updates in scope of this document revision have been approved separately by the required functions/stakeholders through the respective changes. Refer to table below for a description of updates in scope of this document along with a reference to the separate approval of the changes, if needed.

Change PR Number	Change Description	Document Number for Updates	Attachment Number
376171	Irrigation set for France conversion to non DEHP	BXU561782	1

4   REFERENCE DOCUMENTS

Reference Number	Title
N/A	N/A

5   DEFINITIONS

For definitions, see GLOSSARY (Baxter's Glossary).

6   STATEMENT OF INTENDED USE

6.1 Intended Use

Table 1: Access DHF Families & Description

Irrigation Sets	These sets are intended for the delivery of irrigation solutions from the fluid container to the irrigation site during continuous/intermittent bladder irrigation or surgical procedures including but not limited to arthroscopic, gynaecological, obstetrical, gastrointestinal and open wound procedures. These sets come in various configurations including, but not limited to: - Spike (Standard or Easyflow) - Irrigation Chamber (with bubble trapper where applicable) - Clamps - Tubing - Catheter Adaptor - Silicone Tubing

6.2 Use Specification

6.2.1   Intended Users

These sets are used by nurses, physicians, and caregivers, to irrigate drugs/solutions on stable patients and unstable/critically-ill patients with comorbidities; as well as to patients of all age ranges (pediatric/adult/elderly).

6.2.2   Use Environment

These products are used in health care institutions, alternate sites including long term care facilities, skilled nursing facilities, and subacute care facilities, physician offices, free standing centers, hospice, transport/ambulance, and free-standing specialty pharmacies.

7   USER NEEDS

7.1 Product Family: Irrigation Sets

Code: 7400009A

Description: Set for Urological Irrigation

DHF Family: Irrigation Sets

Diagram:

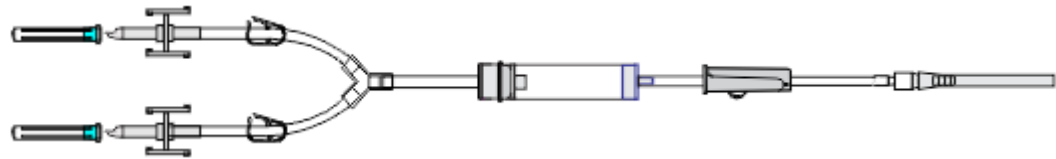| REQUIREMENT ID	USER NEEDS AND INTENDED USES
MAC-UNIU.12	I need to administer irrigation solution to the irrigation site and or surgical sterile field.
MAC-UNIU.18	I need to know when to change my set.
MAC-UNIU.19	I need a set that can be used in a sterile field.
MAC-UNIU.24	I need to be able to use a pressure cuff on the collapsible container to transfer fluids at a higher flow rate.
MAC-UNIU.26	I need a set that is capable of retaining the desired flow rate.
MAC-UNIU.27	I need to be able to regulate to the desire flow rate.
MAC-UNIU.29	I need to be able to see drops falling in the drip chamber.
MAC-UNIU.30	I need to be able to control the flow, turning on and off flow as needed.
MAC-UNIU.31	I need a set with sufficient length for use.
MAC-UNIU.32	I need to be able to prime the set and remove any residual air from the fluid path.
MAC-UNIU.33	I need to be able to administer solution from a collapsible container.
MAC-UNIU.51	I need to identify the directions for use and any cautions of the set
MAC-UNIU.52	I need to be able to read information provided on the product packaging.
MAC-UNIU.54	I need to be able to see the set through the packaging.
MAC-UNIU.55	I need to be able to open the packaging with my hands.
MAC-UNIU.56	I need individually packed sets.
MAC-UNIU.58	I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-UNIU.59	I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-UNIU.60	I need a latex free product.
MAC-UNIU.61	I need to be able to clearly identify the use-by date on the packaging.
MAC-UNIU.148	I need to perform continuous bladder irrigation for up to 72 hours using the same set.

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FORM NO.:   GQT-09-02-01
REVISION: A
ISSUE DATE: 28-DEC-2016
EFFECTIVE DATE: 01-JUL-2017

Code: 7401010A

Description: Y Set for Urological Irrigation

DHF Family: Irrigation Sets

Diagram:

REQUIREMENT ID	USER NEEDS AND INTENDED USES
MAC-UNIU.12	I need to administer irrigation solution to the irrigation site and or surgical sterile field.
MAC-UNIU.18	I need to know when to change my set.
MAC-UNIU.19	I need a set that can be used in a sterile field.
MAC-UNIU.24	I need to be able to use a pressure cuff on the collapsible container to transfer fluids at a higher flow rate.
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MAC-UNIU.32	I need to be able to prime the set and remove any residual air from the fluid path.
MAC-UNIU.33	I need to be able to administer solution from a collapsible container.
MAC-UNIU.37	I need to be able to connect multiple containers, to administer sequential therapies.
MAC-UNIU.51	I need to identify the directions for use and any cautions of the set
MAC-UNIU.52	I need to be able to read information provided on the product packaging.
MAC-UNIU.54	I need to be able to see the set through the packaging.
MAC-UNIU.55	I need to be able to open the packaging with my hands.
MAC-UNIU.56	I need individually packed sets.
MAC-UNIU.58	I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-UNIU.59	I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-UNIU.60	I need a latex free product.
MAC-UNIU.61	I need to be able to clearly identify the use-by date on the packaging.
MAC-UNIU.148	I need to perform continuous bladder irrigation for up to 72 hours using the same set.

PARENT DOCUMENT(S):   GQP-09-02
(current rev.)
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BAXTER CONFIDENTIAL - INTERNAL USE ONLY

FORM NO.:   GQT-09-02-01
REVISION: A
ISSUE DATE: 28-DEC-2016
EFFECTIVE DATE: 01-JUL-2017

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes) User Needs and Intended Use

DOCUMENT NO: BXU535425
REVISION: D

Code: E5MC4002

Description: Single Lead Irrigation Set

DHF Family: Irrigation Sets

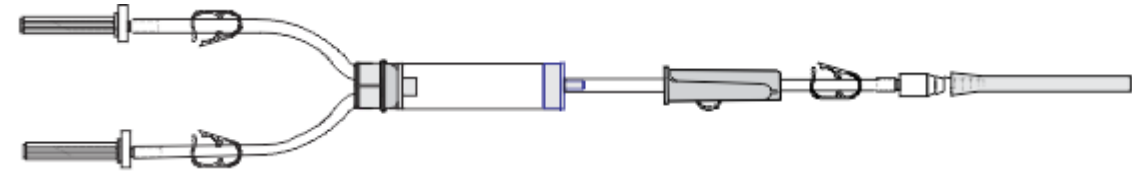**Diagram:**

REQUIREMENT ID	USER NEEDS AND INTENDED USES
MAC-UNIU.12	I need to administer irrigation solution to the irrigation site and or surgical sterile field.
MAC-UNIU.18	I need to know when to change my set.
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MAC-UNIU.54	I need to be able to see the set through the packaging.
MAC-UNIU.55	I need to be able to open the packaging with my hands.
MAC-UNIU.56	I need individually packed sets.
MAC-UNIU.57	I need a Non DEHP set.
MAC-UNIU.58	I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-UNIU.59	I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-UNIU.60	I need a latex free product.
MAC-UNIU.61	I need to be able to clearly identify the use-by date on the packaging.
MAC-UNIU.148	I need to perform continuous bladder irrigation for up to 72 hours using the same set.

PARENT DOCUMENT(S):   GQP-09-02
(current rev.)
OWNER CODE: GQC

FORM NO.:   GQT-09-02-01
REVISION: A
ISSUE DATE: 28-DEC-2016
EFFECTIVE DATE: 01-JUL-2017

Code: E5MC4007N

Description: Y-Type Irrigation Set

DHF Family: Irrigation Sets

Diagram:

REQUIREMENT ID	USER NEEDS AND INTENDED USES
MAC-UNIU.12	I need to administer irrigation solution to the irrigation site and or surgical sterile field.
MAC-UNIU.18	I need to know when to change my set.
MAC-UNIU.19	I need a set that can be used in a sterile field.
MAC-UNIU.24	I need to be able to use a pressure cuff on the collapsible container to transfer fluids at a higher flow rate.
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MAC-UNIU.37	I need to be able to connect multiple containers, to administer sequential therapies.
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MAC-UNIU.55	I need to be able to open the packaging with my hands.
MAC-UNIU.56	I need individually packed sets.
MAC-UNIU.57	I need a Non DEHP set.
MAC-UNIU.58	I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-UNIU.59	I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-UNIU.60	I need a latex free product.
MAC-UNIU.61	I need to be able to clearly identify the use-by date on the packaging.
MAC-UNIU.148	I need to perform continuous bladder irrigation for up to 72 hours using the same set.

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OWNER CODE: GQC

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FORM NO.:   GQT-09-02-01
REVISION: A
ISSUE DATE: 28-DEC-2016
EFFECTIVE DATE: 01-JUL-2017

Code: EMC4002A

Description: Single Lead Irrigation Set

DHF Family: Irrigation Sets

Diagram:

REQUIREMENT ID	USER NEEDS AND INTENDED USES
MAC-UNIU.12	I need to administer irrigation solution to the irrigation site and or surgical sterile field.
MAC-UNIU.18	I need to know when to change my set.
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MAC-UNIU.61	I need to be able to clearly identify the use-by date on the packaging.
MAC-UNIU.148	I need to perform continuous bladder irrigation for up to 72 hours using the same set.

PARENT DOCUMENT(S): GQP-09-02
(current rev.)
OWNER CODE: GQC

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FORM NO.: GQT-09-02-01
REVISION: A
ISSUE DATE: 28-DEC-2016
EFFECTIVE DATE: 01-JUL-2017

Code: EMC4015N

Description: Fast Flow Y-Type Irrigation Set

DHF Family: Irrigation Sets

Diagram:

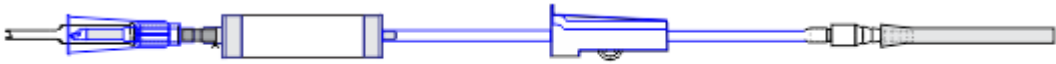| REQUIREMENT ID	USER NEEDS AND INTENDED USES
MAC-UNIU.12	I need to administer irrigation solution to the irrigation site and or surgical sterile field.
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MAC-UNIU.59	I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-UNIU.60	I need a latex free product.
MAC-UNIU.61	I need to be able to clearly identify the use-by date on the packaging.
MAC-UNIU.148	I need to perform continuous bladder irrigation for up to 72 hours using the same set.

PARENT DOCUMENT(S):   GQP-09-02
(current rev.)
OWNER CODE: GQC

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FORM NO.:   GQT-09-02-01
REVISION: A
ISSUE DATE: 28-DEC-2016
EFFECTIVE DATE: 01-JUL-2017

Code: EMC4042

Description: Single Lead Irrigation Set (Easy Flow Uni-Set)

DHF Family: Irrigation Sets

Diagram:

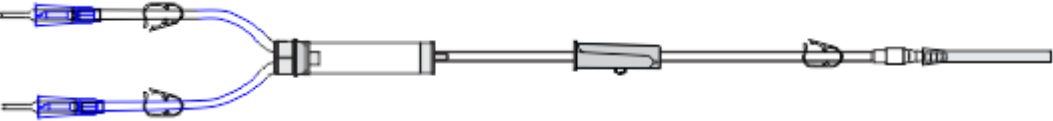| REQUIREMENT ID	USER NEEDS AND INTENDED USES
MAC-UNIU.12	I need to administer irrigation solution to the irrigation site and or surgical sterile field.
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MAC-UNIU.56	I need individually packed sets.
MAC-UNIU.57	I need a Non DEHP set.
MAC-UNIU.58	I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-UNIU.59	I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-UNIU.60	I need a latex free product.
MAC-UNIU.61	I need to be able to clearly identify the use-by date on the packaging.
MAC-UNIU.148	I need to perform continuous bladder irrigation for up to 72 hours using the same set.

PARENT DOCUMENT(S):   GQP-09-02
(current rev.)
OWNER CODE: GQC

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FORM NO.:   GQT-09-02-01
REVISION: A
ISSUE DATE: 28-DEC-2016
EFFECTIVE DATE: 01-JUL-2017

Code: EMC4047

Description: Y-Type Irrigation Set (Easy Flow Multi-Set)

DHF Family: Irrigation Sets

Diagram:

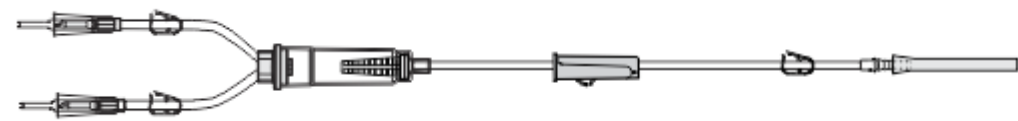| REQUIREMENT ID	USER NEEDS AND INTENDED USES
MAC-UNIU.12	I need to administer irrigation solution to the irrigation site and or surgical sterile field.
MAC-UNIU.18	I need to know when to change my set.
MAC-UNIU.19	I need a set that can be used in a sterile field.
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MAC-UNIU.33	I need to be able to administer solution from a collapsible container.
MAC-UNIU.37	I need to be able to connect multiple containers, to administer sequential therapies.
MAC-UNIU.51	I need to identify the directions for use and any cautions of the set
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MAC-UNIU.55	I need to be able to open the packaging with my hands.
MAC-UNIU.56	I need individually packed sets.
MAC-UNIU.58	I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-UNIU.59	I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-UNIU.60	I need a latex free product.
MAC-UNIU.61	I need to be able to clearly identify the use-by date on the packaging.
MAC-UNIU.148	I need to perform continuous bladder irrigation for up to 72 hours using the same set.

Release Status:Issued and Effective

Code: EMC4055N

Description: Y-Type Irrigation Set (Easy Flow Ultra-Set)

DHF Family: Irrigation Sets

Diagram:

REQUIREMENT ID	USER NEEDS AND INTENDED USES
MAC-UNIU.12	I need to administer irrigation solution to the irrigation site and or surgical sterile field.
MAC-UNIU.18	I need to know when to change my set.
MAC-UNIU.19	I need a set that can be used in a sterile field.
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MAC-UNIU.55	I need to be able to open the packaging with my hands.
MAC-UNIU.56	I need individually packed sets.
MAC-UNIU.57	I need a Non DEHP set.
MAC-UNIU.58	I need to be able to clearly identify if the set contains DEHP plasticizer or not.
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MAC-UNIU.60	I need a latex free product.
MAC-UNIU.61	I need to be able to clearly identify the use-by date on the packaging.
MAC-UNIU.148	I need to perform continuous bladder irrigation for up to 72 hours using the same set.

Release Status:Issued and Effective

Issued Date:18-Mar-2021   Effective Date:18-Mar-2021

BAXTER DHF NO: 81548-DHF-ERD   DOCUMENT NO: BXU535425
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes) User Needs and Intended Use   REVISION: D

Code: RMC4916

Description: Irrigation Set
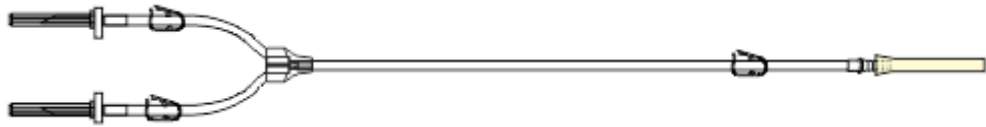
DHF Family: Irrigation Sets

Diagram:

REQUIREMENT ID	USER NEEDS AND INTENDED USES
MAC-UNIU.12	I need to administer irrigation solution to the irrigation site and or surgical sterile field.
MAC-UNIU.19	I need a set that can be used in a sterile field.
MAC-UNIU.33	I need to be able to administer solution from a collapsible container.
MAC-UNIU.51	I need to identify the directions for use and any cautions of the set
MAC-UNIU.52	I need to be able to read information provided on the product packaging.
MAC-UNIU.54	I need to be able to see the set through the packaging.
MAC-UNIU.55	I need to be able to open the packaging with my hands.
MAC-UNIU.56	I need individually packed sets.
MAC-UNIU.58	I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-UNIU.59	I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-UNIU.60	I need a latex free product.
MAC-UNIU.61	I need to be able to clearly identify the use-by date on the packaging.

Code: VMC4005

Description: Y-Type Irrigation Set

DHF Family: Irrigation Sets

Diagram:

REQUIREMENT ID	USER NEEDS AND INTENDED USES
MAC-UNIU.12	I need to administer irrigation solution to the irrigation site and or surgical sterile field.
MAC-UNIU.18	I need to know when to change my set.
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MAC-UNIU.55	I need to be able to open the packaging with my hands.
MAC-UNIU.56	I need individually packed sets.
MAC-UNIU.57	I need a Non DEHP set.
MAC-UNIU.58	I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-UNIU.59	I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-UNIU.60	I need a latex free product.
MAC-UNIU.61	I need to be able to clearly identify the use-by date on the packaging.
MAC-UNIU.148	I need to perform continuous bladder irrigation for up to 72 hours using the same set.

PARENT DOCUMENT(S):   GQP-09-02
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FORM NO.:   GQT-09-02-01
REVISION: A
ISSUE DATE: 28-DEC-2016
EFFECTIVE DATE: 01-JUL-2017

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes) User Needs and Intended Use

DOCUMENT NO: BXU535425
REVISION: D

8 REVISION HISTORY

REVISION	ISSUE DATE	REASON FOR CHANGE
A	Refer to Stamp	New Document
B	Refer to Stamp	Irrigation Change History B
C	Refer to Stamp	Correction of entry errors from previous revision
D	Refer to Stamp	As per Change Control-2014-006542(PR#376171)

Release Status:Issued and Effective

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TcU ELECTRONIC SIGNATURE REPORT

REVISION INFORMATION	
Item ID: BXU535425	**Revision ID:** D
Item Name: IRRIGATION SETS (MALTA ACCESS CODES) USER NEEDS AND INTENDED USE	**Release Date:** 18-Mar-2021
Description:	

CHANGE INFORMATION
CN/CR Number (if applicable):
Description of Change (This field will be blank if required data is not available): As per Change Control-2014-006542(PR#376171)
Reason for Change (This field will be blank if required data is not available): As per Change Control-2014-006542(PR#376171)

APPROVALS & SIGNATURES for Document Release				
Name	**Role**	**Workflow Step**	**Date of Signature**	**Decision Taken**
Jordan, Simon	SME	Initiate Review	17-Mar-2021	Approved
Jordan, Simon	SME	Document Review - SME & Quality	17-Mar-2021	Approved
Psaila, Cynthia	Quality	Document Review - SME & Quality	17-Mar-2021	Approved
Cachia, Diane	Change Specialist 3	Release Document(s)	18-Mar-2021	Approved
Cachia, Diane	Change Specialist 3	Set Effectivity	18-Mar-2021	Approved

Release Status:Issued and Effective