BAHT statement on the provision of custom made and off the shelf splints under MHRA Regulations. August 2021.

The Medical and Healthcare products Regulatory Agency (MHRA) is the Government organisation that monitors and regulates medicines, medical devices and blood components in the UK.

MHRA are also responsible for Medical Device Regulations (MDR) which covers off the shelf devices and thermoplastic custom moulded splints that Hand Therapists provide for a medical purpose.

Post-Brexit changes to Medical Device Regulations (MDR) have led to uncertainty amongst hand therapists and BAHT would like to provide the following guidance and reassurance to hand therapists working in the NHS.

Pre-Fabricated devices / splints

Prefabricated/off the shelf splints need to display the current CE safety mark. This will be accepted until June 2023, after which the UKCA mark will need to be applied. Manufacturers of prefabricated devices need to meet the requirements of the UK Medical Device Regulations 2002. **A therapist using a CE/UKCA marked splint and adjusting to fit for an individual patient holds no additional regulatory requirements as long as the device is used according to manufacturer instruction and intentio**n.

Pressure Garments

When we write a prescription for custom made pressure garments, the company producing the garment is the legal manufacturer. The legal manufacturer needs to meet the regulatory requirements for custom made medical devices. They will need to register with MHRA if they have not already done so and supply the relevant declarations. In-house manufactured pressure garments would fall under custom made device advice below.

Custom-made Devices / Splints

Splints manufactured by therapists in-house and provided to patients within your Trust, are subject to in house exemption. Splints must not be put onto the market or put into service outside your Trust. Any prefabricated components should be CE/UKCA marked. Thermoplastics supplied as raw materials (e.g. as rolls or sheets of material) from which to manufacture the splints are unlikely to be regarded as medical devices in their own right.

Documentation

MDR recommend that medical professionals providing medical devices should record the following information for each product they prescribe to a patient (indicated in bold font). This information should enable the repeatable provision and tracking of the product. Additional guidance from BAHT for each MDR recommendation is provided in italics.

The written record / prescription should detail:

1. **data allowing identification of the device in question, i.e. description, serial number, order number, generic name.**

- *additional information: record the accepted generic name of the splint and detail of material used. Where relevant, the serial/batch number of the splint material should be documented as this allows exact tracing back to the product.*

2. **a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient (this may be an identification number if patient confidentiality needs to be maintained, provided it can be traced through records to the named patient)**
    - *additional information: the patient record should document that the device is for the exclusive use of that particular patient. This should be explicit on written patient information provided with every device.*

3. **the name of the qualified person, medical practitioner or other authorised person who made out the prescription and, where applicable, their place of work**
    - *additional information: the device 'prescription' will be recorded in the patient therapy/medical notes and entry signed off by the prescriber.*

4. **the particular features of the device as specified in the relevant prescription, i.e., the written prescription with its special features extracted to define the particular device.**
    - *additional information: this should include detail such as position of limb/joint(s) within the splint, whether the inserts (metal or plastic) from off the shelf splints have been adjusted & if so how, or removed.*
    - *from this information a medical professional should be able to repeat the prescription of the product from the detail documented in the patient record.*

5. **a statement that the device in question conforms to all the relevant essential requirements and, where it does not, the grounds for believing it is safe for use.**
    - *additional information: this could be a department statement that the off the shelf & thermoplastic splints provided conform to essential requirements i.e. CE/UKCA marked and used in line with manufacturer recommendations. This can be added to the patient information leaflet which is issued with the device.*

6. **the name and address of the manufacturer**
    - *additional information: the distributor's company name is sufficient to hold within the therapy department records.*

Examples:

1. A volar wrist extension / cock-up splint using 3.2mm xxx material manufactured and fitted for exclusive use of Joe Bloggs. Moulded over cotton stockinette with additional provided. Wrist extension of 30 degrees achieved and digits unrestricted. Splint secured with 3x hook and loop / Velcro straps and additional stockinette provided for use under the splint . As prescribed by XX therapist (signed and dated). A patient information leaflet should be provided with every splint issued.

2. Elastic wrist brace medium left (brand name) fitted for exclusive use of Josie Bloggs. Volar extension bar adjusted to increase wrist extension to 30 degrees as prescribed by XX therapist (signed and dated). A patient information leaflet advising that off the shelf splints meet CE / UKCA safety requirements.

Or consider using a template:

This splint has been provided for exclusive use of (patient name)

Splint Name	*Hand Resting Splint*
Material	*3.2mm XXX*
Position	*Volar hand and forearm based. Wrist 20 ext, MCP's 50 flex, IP's -10 ext*
Fastening	*3x Hook and Loop Straps*
Wearing Instructions	*Overnight and daytime rest periods*
Additional Information	*Stockinette provided for use with splint* *Patient aware to check skin for pressure areas* *Written information leaflet provided*

For further information please refer to the links below:

https://www.gov.uk/government/publications/custom-made-medical-devices/custom-made-devices-in-great-britain

https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices/in-house-manufacture-of-medical-devices

The information provided is based on our best judgement of the information available and subject to change. This is not a definitive statement of law and we advise you to seek the views of your own professional advisors.